ANNEX I

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTES OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Risperdal Quicklet 0,5 mg - Tabletten	0,5 mg	Orodispersible tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Risperdal Quicklet 1mg - Tabletten	1 mg	Orodispersible tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Risperdal Quicklet 2 mg - Tabletten	2 mg	Orodispersible tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Risperdal Quicklet 3 mg - Tabletten	3 mg	Orodispersible tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Risperdal Quicklet 4 mg - Tabletten	4 mg	Orodispersible tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Risperdal 0,5 mg - Filmtabletten	0,5 mg	Film-coated tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Risperdal 1 mg - Filmtabletten	1 mg	Film-coated tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Risperdal 2 mg - Filmtabletten	2 mg	Film-coated tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Risperdal 3 mg - Filmtabletten	3 mg	Film-coated tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Risperdal 4 mg - Filmtabletten	4 mg	Film-coated tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Risperdal 6 mg - Filmtabletten	6 mg	Film-coated tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Risperdal 1 mg/ml - orale Lösung	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Rispolin Quicklet 0,5 mg - Tabletten	0,5 mg	Orodispersible tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Rispolin Quicklet 1 mg - Tabletten	1 mg	Orodispersible tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Rispolin Quicklet 2 mg - Tabletten	2 mg	Orodispersible tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Rispolin Quicklet 3 mg - Tabletten	3 mg	Orodispersible tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Rispolin Quicklet 4 mg - Tabletten	4 mg	Orodispersible tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Rispolin 0,5 mg - Filmtabletten	0,5 mg	Film-coated tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Rispolin 1 mg- Filmtabletten	1 mg	Film-coated tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Rispolin 2 mg - Filmtabletten	2 mg	Film-coated tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Rispolin 3 mg - Filmtabletten	3 mg	Film-coated tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Rispolin 4 mg - Filmtabletten	4 mg	Film-coated tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Rispolin 6 mg - Filmtabletten	6 mg	Film-coated tablet	Oral use	
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien Austria	Risperidon	Rispolin 1 mg/ml - orale Lösung	1 mg	Oral solution	Oral use	1 mg/ 1 ml

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600 Berchem Belgium	Risperidone	Risperidone J-C Instasolv	0.5 mg	Orodispersible tablet	Oral use	
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600 Berchem, Belgium	Risperidone	Risperdal	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600 Berchem, Belgium	Risperidone	Risperdal	0.5 mg	Film-coated tablet	Oral use	
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600 Berchem, Belgium	Risperidone	Risperdal	1 mg	Film-coated tablet	Oral use	
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600 Berchem, Belgium	Risperidone	Risperdal	2 mg	Film-coated tablet	Oral use	
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600 Berchem, Belgium	Risperidone	Risperdal	3 mg	Film-coated tablet	Oral use	
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600 Berchem, Belgium	Risperidone	Risperdal	4 mg	Film-coated tablet	Oral use	
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600 Berchem, Belgium	Risperidone	Risperdal	6 mg	Film-coated tablet	Oral use	
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600 Berchem, Belgium	Risperidone	Risperdal Instasolv	0.5 mg	Orodispersible tablet	Oral use	
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600 Berchem, Belgium	Risperidone	Risperdal Instasolv	1 mg	Orodispersible tablet	Oral use	
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600	Risperidone	Risperdal Instasolv	2 mg	Orodispersible tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	Berchem, Belgium						
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600 Berchem, Belgium	Risperidone	Risperidone J-C	0.5 mg	Film-coated tablet	Oral use	
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600 Berchem, Belgium	Risperidone	Risperidone J-C	1 mg	Film-coated tablet	Oral use	
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600 Berchem, Belgium	Risperidone	Risperidone J-C	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600 Berchem, Belgium	Risperidone	Risperidone J-C	2 mg	Film-coated tablet	Oral use	
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600 Berchem, Belgium	Risperidone	Risperidone J-C	3 mg	Film-coated tablet	Oral use	
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600 Berchem, Belgium	Risperidone	Risperidone J-C	4 mg	Film-coated tablet	Oral use	
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600 Berchem, Belgium	Risperidone	Risperidone J-C	6 mg	Film-coated tablet	Oral use	
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600 Berchem, Belgium	Risperidone	Risperidone J-C Instasolv	1 mg	Orodispersible tablet	Oral use	
Belgium	Janssen Cilag N.V. Roderveldlaan 1 B-2600 Berchem, Belgium	Risperidone	Risperidone J-C Instasolv	2 mg	Orodispersible tablet	Oral use	
Bulgaria	Johnson & Johnson D.O.O. Smartinska cesta 53 1000 Ljubljana Slovenia	Risperidone	Rispolept	1mg	Oral solution	Oral use	1 mg/ 1 ml

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Bulgaria	Johnson & Johnson D.O.O. Smartinska cesta 53, 1000 Ljubljana, Slovenia	Risperidone	Rispolept	1 mg	Film coated tablet	Oral use	
Bulgaria	Johnson & Johnson D.O.O. Smartinska cesta 53, 1000 Ljubljana, Slovenia	Risperidone	Rispolept	2 mg	Film coated tablet	Oral use	
Bulgaria	Johnson & Johnson D.O.O. Smartinska cesta 53, 1000 Ljubljana, Slovenia	Risperidone	Rispolept	3 mg	Film coated tablet	Oral use	
Bulgaria	Johnson & Johnson D.O.O. Smartinska cesta 53, 1000 Ljubljana, Slovenia	Risperidone	Rispolept	4 mg	Film coated tablet	Oral use	
Cyprus	Janssen-Cilag International NV, Turnhoutseweg 30, B-2340, Beerse, Belgium	Risperidone	Risperdal	1 mg	Film-coated tablets	Oral use	
Cyprus	Janssen-Cilag International NV, Turnhoutseweg 30, B-2340, Beerse, Belgium	Risperidone	Risperdal	2 mg	Film-coated tablets	Oral use	
Cyprus	J Janssen-Cilag International NV, Turnhoutseweg 30, B-2340, Beerse, Belgium	Risperidone	Risperdal	3 mg	Film-coated tablets	Oral use	
Cyprus	Janssen-Cilag International NV, Turnhoutseweg 30, B-2340, Beerse, Belgium	Risperidone	Risperdal	4mg	Film-coated tablets	Oral use	
Cyprus	Janssen-Cilag International NV, Turnhoutseweg 30, B-2340, Beerse, Belgium	Risperidone	Risperdal	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Czech Republic	Janssen-Cilag s.r.o. Karla Engliše 3201/6 150 00 Praha 5 Czech Republic	Risperidonum	Risperdal 1 mg	1 mg	Film-coated tablet	oral use	
Czech Republic	Janssen-Cilag s.r.o. Karla Engliše 3201/6	Risperidonum	Risperdal 2 mg	2 mg	Film-coated tablet	oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	150 00 Praha 5						
Czech Republic	Janssen-Cilag s.r.o. Karla Engliše 3201/6 150 00 Praha 5	Risperidonum	Risperdal 3 mg	3 mg	Film-coated tablet	oral use	
Czech Republic	Janssen-Cilag s.r.o. Karla Engliše 3201/6 150 00 Praha 5	Risperidonum	Risperdal 4 mg	4 mg	Film-coated tablet	oral use	
Czech Republic	Janssen-Cilag s.r.o. Karla Engliše 3201/6 150 00 Praha 5	Risperidonum	Risperdal	1 mg	Oral solution	oral use	1 mg/ 1 ml
Czech Republic	Janssen-Cilag s.r.o. Karla Engliše 3201/6 150 00 Praha 5	Risperidonum	Risperdal Quicklet	2 mg	Orodispersible tablet	oral use	
Czech Republic	Janssen-Cilag s.r.o. Karla Engliše 3201/6 150 00 Praha 5	Risperidonum		3 mg	Orodispersible tablet		
Czech Republic	Janssen-Cilag s.r.o. Karla Engliše 3201/6 150 00 Praha 5	Risperidonum	Risperdal Quicklet	4 mg	Orodispersible tablet	oral use	
Denmark	Janssen-Cilag A/S Postboks 149 Hammerbakken 19 3460 Birkerød Denmark	Risperidone	Belivon	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Denmark	Janssen-Cilag A/S, Postboks 149, Hammerbakken 19, 3460 Birkerød, Denmark	Risperidone	Belivon	1 mg	Film-coated	Oral use	
Denmark	Janssen-Cilag A/S, Postboks 149, Hammerbakken 19, 3460 Birkerød, Denmark	Risperidone	Belivon	2 mg	Film-coated	Oral use	
Denmark	Janssen-Cilag A/S, Postboks 149, Hammerbakken 19, 3460	Risperidone	Belivon	3 mg	Film-coated	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	Birkerød, Denmark						
Denmark	Janssen-Cilag A/S, Postboks 149, Hammerbakken 19, 3460 Birkerød, Denmark	Risperidone	Belivon	4 mg	Film-coated	Oral use	
Denmark	Janssen-Cilag A/S, Postboks 149, Hammerbakken 19, 3460 Birkerød, Denmark	Risperidone	Risperdal	0,5 mg	Film-coated tablets	Oral use	
Denmark	Janssen-Cilag A/S, Postboks 149, Hammerbakken 19, 3460 Birkerød, Denmark	Risperidone	Risperdal	1 mg	Film-coated tablets	Oral use	
Denmark	Janssen-Cilag A/S , Postboks 149, Hammerbakken 19, 3460 Birkerød, Denmark	Risperidone	Risperdal	2 mg	Film-coated tablets	Oral use	
Denmark	Janssen-Cilag A/S , Postboks 149, Hammerbakken 19, 3460 Birkerød, Denmark	Risperidone	Risperdal	3 mg	Film-coated tablets	Oral use	
Denmark	Janssen-Cilag A/S , Postboks 149, Hammerbakken 19, 3460 Birkerød, Denmark	Risperidone	Risperdal	4 mg	Film-coated tablets	Oral use	
Denmark	Janssen-Cilag A/S , Postboks 149, Hammerbakken 19, 3460 Birkerød, Denmark	Risperidone	Risperdal	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Denmark	Janssen-Cilag A/S , Postboks 149, Hammerbakken 19, 3460 Birkerød, Denmark	Risperidone	Risperdal	0,5 mg	Oral lyophilisate	Oral use	
Denmark	Janssen-Cilag A/S , Postboks 149, Hammerbakken 19, 3460 Birkerød, Denmark	Risperidone	Risperdal	1 mg	Oral lyophilisate	Oral use	
Denmark	Janssen-Cilag A/S Postboks 149 Hammerbakken 19 3460 Birkerød	Risperidone	Risperdal	2 mg	Oral lyophilisate	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	Denmark						
Estonia	Johnson & Johnson UAB Šeimyniškių g. 1A LT-09312 Vilnius Lithuania	Risperidone	Rispolept	1 mg	Film-coated tablet	Oral use	
Estonia	Johnson & Johnson UAB Šeimyniškių g. 1A LT-09312 Vilnius Lithuania	Risperidone	Rispolept	2 mg	Film-coated tablet	Oral use	
Estonia	Johnson & Johnson UAB Šeimyniškių g. 1A LT-09312 Vilnius Lithuania	Risperidone	Rispolept	3 mg	Film-coated tablet	Oral use	
Estonia	Johnson & Johnson UAB Šeimyniškių g. 1A LT-09312 Vilnius Lithuania	Risperidone	Rispolept	4 mg	Film-coated tablet	Oral use	
Estonia	Johnson & Johnson UAB Šeimyniškių g. 1A LT-09312 Vilnius Lithuania	Risperidone	Rispolept	1 mg/ml	Oral solution	Oral use	1 mg/ 1 ml
Estonia	Johnson & Johnson UAB Šeimyniškių g. 1A LT-09312 Vilnius Lithuania	Risperidone	Rispolept Quicklet	1 mg	Orodispersible tablet	Oral use	
Estonia	Johnson & Johnson UAB Šeimyniškių g. 1A LT-09312 Vilnius Lithuania	Risperidone	Rispolept Quicklet	2 mg	Orodispersible tablet	Oral use	
Finland	Jansen-Cilag Oy Metsänneidonkuja 8 02130 Espoo	Risperidone	Risperdal	1 mg	Oral solution	Oral use	1 mg/ 1 ml

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	Finland						
Finland	Jansen-Cilag Oy Metsänneidonkuja 8 02130 Espoo Finland	Risperidone	Risperdal	0.25 mg	Film-coated tablet	Oral use	
Finland	Jansen-Cilag Oy Metsänneidonkuja 8 02130 Espoo Finland	Risperidone	Risperdal	0.5 mg	Film-coated tablet	Oral use	
Finland	Jansen-Cilag Oy Metsänneidonkuja 8 02130 Espoo Finland	Risperidone	Risperdal	1 mg	Film-coated tablet	Oral use	
Finland	Jansen-Cilag Oy Metsänneidonkuja 8 02130 Espoo Finland	Risperidone	Risperdal	2 mg	Film-coated tablet	Oral use	
Finland	Jansen-Cilag Oy Metsänneidonkuja 8 02130 Espoo Finland	Risperidone	Risperdal	3 mg	Film-coated tablet	Oral use	
Finland	Jansen-Cilag Oy Metsänneidonkuja 8 02130 Espoo Finland	Risperidone	Risperdal	4 mg	Film-coated tablet	Oral use	
Finland	Jansen-Cilag Oy Metsänneidonkuja 8 02130 Espoo Finland	Risperidone	Risperdal	6 mg	Film-coated tablet	Oral use	
Finland	Jansen-Cilag Oy Metsänneidonkuja 8 02130 Espoo Finland	Risperidone	Risperdal Instasolv	0.5 mg	Orodispersible tablet	Oral use	
Finland	Jansen-Cilag Oy Metsänneidonkuja 8 02130 Espoo Finland	Risperidone	Risperdal Instasolv	1 mg	Orodispersible tablet	Oral use	
Finland	Jansen-Cilag Oy Metsänneidonkuja 8 02130 Espoo Finland	Risperidone	Risperdal Instasolv	2 mg	Orodispersible tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Finland	Jansen-Cilag Oy Metsänneidonkuja 8 02130 Espoo Finland	Risperidone	Risperdal Instasolv	3 mg	Orodispersible tablet	Oral use	
Finland	Jansen-Cilag Oy Metsänneidonkuja 8 02130 Espoo Finland	Risperidone	Risperdal Instasolv	4 mg	Orodispersible tablet	Oral use	
France	Laboratorires Janssen Cilag 1 rue Desmoulins TSA 91003 92787 Issy les Moulineaux Cedex 9, France	Risperidone	Belivon	1 mg	Scored tablet	Oral use	
France	Laboratorires Janssen Cilag 1 rue Desmoulins TSA 91003 92787 Issy les Moulineaux Cedex 9, France	Risperidone	Belivon	2 mg	Scored tablet	Oral use	
France	Laboratorires Janssen Cilag 1 rue Desmoulins TSA 91003 92787 Issy les Moulineaux Cedex 9, France	Risperidone	Belivon	3 mg	Scored tablet	Oral use	
France	Laboratoires Janssen Cilag 1 rue Desmoulins TSA 91003 92787 Issy les Moulineaux Cedex 9, France	Risperidone	Belivon	4 mg	Scored tablet	Oral use	
France	Laboratoires Janssen Cilag 1 rue Desmoulins TSA 91003 92787 Issy les Moulineaux Cedex 9, France	Risperidone	Risperdal	0.5 mg	Film coatedtablet	Oral use	
France	Laboratoires Janssen Cilag 1 rue Desmoulins	Risperidone	Risperdal	1 mg	Half-Scored tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	TSA 91003 92787 Issy les Moulineaux Cedex 9, France						
France	Laboratoires Janssen Cilag 1 rue Desmoulins TSA 91003 92787 Issy les Moulineaux Cedex 9, France	Risperidone	Risperdal	2 mg	Half-Scored tablet	Oral use	
France	Laboratoires Janssen Cilag 1 rue Desmoulins TSA 91003 92787 Issy les Moulineaux Cedex 9, France	Risperidone	Risperdal	3 mg	Half-Scored tablet	Oral use	
France	Laboratoires Janssen Cilag 1 rue Desmoulins TSA 91003 92787 Issy les Moulineaux Cedex 9, France	Risperidone	Risperdal	4 mg	Half-Scored tablet	Oral use	
France	Laboratoires Janssen Cilag 1 rue Desmoulins TSA 91003 92787 Issy les Moulineaux Cedex 9, France	Risperidone	Risperdal	1mg/ml	Oral solution	Oral use	1 mg/ 1 ml
France	Laboratoires Janssen Cilag 1 rue Desmoulins TSA 91003 92787 Issy les Moulineaux Cedex 9, France	Risperidone	Risperdaloro	0.5 mg	Orodispersible Tablet	Oral use	
France	Laboratoires Janssen Cilag 1 rue Desmoulins TSA 91003 92787 Issy les Moulineaux Cedex 9, France	Risperidone	Risperdaloro	1 mg	Orodispersible Tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
France	Laboratoires Janssen Cilag 1 rue Desmoulins TSA 91003 92787 Issy les Moulineaux Cedex 9, France	Risperidone	Risperdaloro	2 mg	Orodispersible Tablet	Oral use	
France	Laboratoires Janssen Cilag 1 rue Desmoulins TSA 91003 92787 Issy les Moulineaux Cedex 9, France	Risperidone	Risperdaloro	3 mg	Orodispersible Tablet	Oral use	
France	Laboratoires Janssen Cilag 1 rue Desmoulins TSA 91003 92787 Issy les Moulineaux Cedex 9, France	Risperidone	Risperdaloro	4 mg	Orodispersible Tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Risperdal 1 mg	1 mg	Film-coated tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Risperdal 2 mg	2 mg	Film-coated tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Risperdal 3 mg	3 mg	Film-coated tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Risperdal 4 mg	4 mg	Film-coated tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Risperdal Filmtabletten 0,25 mg	0.25 mg	Film-coated tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Risperdal Filmtabletten 0,5 mg	0.5 mg	Film-coated tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Risperdal Filmtabletten 6 mg	6 mg	Film-coated tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Risperdal Lösung 1 mg/ml	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Germany	Janssen-Cilag GmbH 41457 Neuss or	Risperidon	Risperdal Quicklet 1 mg	1 mg	Orodispersible tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany						
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Risperdal Quicklet 2 mg	2 mg	Orodispersible tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Risperdal Quicklet 3 mg	3 mg	Orodispersible tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Risperdal Quicklet 4 mg	4 mg	Orodispersible tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Risperidon-Janssen Filmtabletten 6 mg	6 mg	Film-coated tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Risperidon-Janssen Loesung 1 mg/ml	1 mg	Oral solution	Oral use	1 mg/ 1 ml

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Belivon 0,5 mg Filmtabletten	0.5 mg	Film-coated tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Belivon 1 mg Filmtabletten	1 mg	Film-coated tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Belivon 1mg/ml Lösung	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Belivon 2 mg Filmtabletten	2 mg	Film-coated tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Belivon 3 mg Filmtabletten	3 mg	Film-coated tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Belivon 4 mg Filmtabletten	4 mg	Film-coated tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Belivon 6 mg Filmtabletten	6 mg	Film-coated tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Rehablit 1 mg	1 mg	Film-coated tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss. Germany	Risperidon	Rehablit 2 mg	2 mg	Film-coated tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Rehablit 3 mg	3 mg	Film-coated tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss	Risperidon	Rehablit 4 mg	4 mg	Film-coated tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany						
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Rehablit Filmtabletten 6 mg	6 mg	Film-coated tablet	Oral use	
Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen-Cilag GmbH Raiffeisenstr. 8 41470 Neuss, Germany	Risperidon	Rehablit Lösung 1 mg/ml	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Greece	Janssen-Cilag Pharmaceutical S.A.C.I 56 Eirinis Avenue 56 Pefki, 15121 Greece	Risperidone	Risperdal	1 mg	Film-coated tablet	Oral use	
Greece	Janssen-Cilag Pharmaceutical S.A.C.I, 56 Eirinis Avenue, Pefki, 15121, Greece	Risperidone	Risperdal	2 mg	Film-coated tablet	Oral use	
Greece	Janssen-Cilag Pharmaceutical S.A.C.I, 56 Eirinis Avenue, Pefki, 15121, Greece	Risperidone	Risperdal	3 mg	Film-coated tablet	Oral use	
Greece	Janssen-Cilag Pharmaceutical S.A.C.I, 56 Eirinis Avenue, Pefki, 15121, Greece	Risperidone	Risperdal	4 mg	Film-coated tablet	Oral use	
Greece	Janssen-Cilag Pharmaceutical S.A.C.I, 56 Eirinis Avenue, Pefki, 15121, Greece	Risperidone	Risperdal	6 mg	Film-coated tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Greece	Janssen-Cilag Pharmaceutical S.A.C.I, 56 Eirinis Avenue, Pefki, 15121, Greece	Risperidone	Risperdal	8 mg	Film-coated tablet	Oral use	
Greece	Janssen-Cilag Pharmaceutical S.A.C.I, 56 Eirinis Avenue, Pefki, 15121, Greece	Risperidone	Risperdal	1 mg/1 ml	Oral Solution	Oral use	1 mg/ 1 ml
Greece	Janssen-Cilag Pharmaceutical S.A.C.I, 56 Eirinis Avenue, Pefki, 15121, Greece	Risperidone	Risperdal Quicklet	0.5 mg	Lingual tablet	Oral use	
Greece	Janssen-Cilag Pharmaceutical S.A.C.I, 56 Eirinis Avenue, Pefki, 15121, Greece	Risperidone	Risperdal Quicklet	1 mg	Lingual tablet	Oral use	
Greece	Janssen-Cilag Pharmaceutical S.A.C.I, 56 Eirinis Avenue, Pefki, 15121, Greece	Risperidone	Risperdal Quicklet	2 mg	Lingual tablet	Oral use	
Greece	Janssen-Cilag Pharmaceutical S.A.C.I, 56 Eirinis Avenue, Pefki, 15121, Greece	Risperidone	Risperdal Quicklet	3 mg	Lingual tablet	Oral use	
Greece	Janssen-Cilag Pharmaceutical S.A.C.I, 56 Eirinis Avenue, Pefki, 15121, Greece	Risperidone	Risperdal Quicklet	4 mg	Lingual tablet	Oral use	
Hungary	Janssen- Cilag Kft. 2045 Törökbálint Tó park Hungary	Risperidone	Risperdal	1 mg	Film coated tablet	Oral use	
Hungary	Janssen- Cilag Kft. 2045 Törökbálint Tó park, Hungary	Risperidone	Risperdal	2 mg	Film coated tablet	Oral use	
Hungary	Janssen- Cilag Kft. 2045 Törökbálint Tó park, Hungary	Risperidone	Risperdal	3 mg	Film coated tablet	Oral use	
Hungary	Janssen- Cilag Kft. 2045 Törökbálint Tó park, Hungary	Risperidone	Risperdal	4 mg	Film coated tablet	Oral use	
Hungary	Janssen- Cilag Kft. 2045 Törökbálint Tó park, Hungary	Risperidone	Risperdal	1mg	Oral solution	Oral use	1 mg/ 1 ml

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Hungary	Janssen- Cilag Kft. 2045 Törökbálint Tó park, Hungary	Risperidone	Risperdal Quicklet	2 mg	Orodispersible tablet	Oral use	
Hungary	Janssen- Cilag Kft. 2045 Törökbálint Tó park, Hungary	Risperidone	Risperdal Quicklet	3 mg	Orodispersible tablet	Oral use	
Hungary	Janssen- Cilag Kft. 2045 Törökbálint Tó park Hungary	Risperidone	Risperdal Quicklet	4 mg	Orodispersible tablet	Oral use	
Iceland	Janssen-Cilag AB Box 7073 192 07 Sollentuna Sverige	Risperidonum	Risperdal	0,5 mg	Oral lyophilisate	Oral use	
Iceland	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidonum	Risperdal	1 mg	Oral lyophilisate	Oral use	
Iceland	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidonum	Risperdal	2 mg	Oral lyophilisate	Oral use	
Iceland	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidonum	Risperdal	3 mg	Oral lyophilisate	Oral use	
Iceland	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidonum	Risperdal	4 mg	Oral lyophilisate	Oral use	
Iceland	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidonum	Risperdal	0,5 mg	Film coated tablet	Oral use	
Iceland	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidonum	Risperdal	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Iceland	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidonum	Risperdal	1 mg	Film Coated tablet	Oral use	
Iceland	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidonum	Risperdal	2 mg	Film Coated tablet	Oral use	
Iceland	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidonum	Risperdal	3 mg	Film Coated tablet	Oral use	
Iceland	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidonum	Risperdal	4 mg	Film Coated tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Ireland	Janssen-Cilag Ltd Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal Liquid	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Ireland	Janssen-Cilag Ltd Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal	6 mg	Film Coated Tablet	Oral use	
Ireland	Janssen-Cilag Ltd Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal	1 mg	Film Coated Tablet	Oral use	
Ireland	Janssen-Cilag Ltd Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal	2 mg	Film Coated Tablet	Oral use	
Ireland	Janssen-Cilag Ltd Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal	3 mg	Film Coated Tablet	Oral use	
Ireland	Janssen-Cilag Ltd Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal	4 mg	Film Coated Tablet	Oral use	
Ireland	Janssen-Cilag Ltd Saunderton High Wycombe	Risperidone	Risperdal	0.25 mg	Film Coated Tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	Buckinghamshire HP14 4HJ United Kingdom						
Ireland	Janssen-Cilag Ltd Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal	0.5 mg	Film Coated Tablet	Oral use	
Ireland	Janssen-Cilag Ltd Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal Quicklet	0.5 mg	Orodispersible tablet	Oral use	
Ireland	Janssen-Cilag Ltd Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal Quicklet	1 mg	Orodispersible tablet	Oral use	
Ireland	Janssen-Cilag Ltd Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal Quicklet	2 mg	Orodispersible tablet	Oral use	
Ireland	Janssen-Cilag Ltd Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal Quicklet	3 mg	Orodispersible tablet	Oral use	
Ireland	Janssen-Cilag Ltd Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal Quicklet	4 mg	Orodispersible tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Italy	Janssen Cilag Spa Via Michelangelo Buonarroti n. 23 Cologno Monzese 20093, Milano Italy	Risperidone	Risperdal	1 mg	Film coated tablet	Oral use	
Italy	Janssen Cilag Spa Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	Risperidone	Risperdal	2 mg	Film coated tablet	Oral use	
Italy	Janssen Cilag Spa Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	Risperidone	Risperdal	3 mg	Film coated tablet	Oral use	
Italy	Janssen Cilag Spa Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	Risperidone	Risperdal	4 mg	Film coated tablet	Oral use	
Italy	Janssen Cilag Spa Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	Risperidone	Risperdal	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Italy	Janssen Cilag Spa Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	Risperidone	Risperdal	0,5 mg	Tablet	Oral use	
Italy	Janssen Cilag Spa Via Michelangelo Buonarroti n.	Risperidone	Risperdal	0,25 mg	Tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	23 Cologno Monzese, 20093, Milano, Italy						
Italy	Janssen Cilag Spa Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	Risperidone	Risperdal	6 mg	Film coated tablet	Oral use	
Italy	Janssen Cilag Spa Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	Risperidone	Risperdal	0,5 mg	Orodispersible tablet	Oral	
Italy	Janssen Cilag Spa Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	Risperidone	Risperdal	1 mg	Orodispersible tablet	Oral use	
Italy	Janssen Cilag Spa Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	Risperidone	Risperdal	2 mg	Orodispersible tablet	Oral use	
Italy	J.C. HEALTHCARE srl Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	Risperidone	BELIVON	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Italy	J.C. HEALTHCARE srl Via Michelangelo Buonarroti n. 23 Cologno Monzese	Risperidone	BELIVON	1 mg	Film coated tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	20093 Milano Italy						
Italy	J.C. HEALTHCARE srl Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	Risperidone	BELIVON	2 mg	Film coated tablet	Oral use	
Italy	J.C. HEALTHCARE srl Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	Risperidone	BELIVON	3 mg	Film coated tablet	Oral use	
Italy	J.C. HEALTHCARE srl Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	Risperidone	BELIVON	4 mg	Film coated tablet	Oral use	
Italy	J.C. HEALTHCARE srl Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	Risperidone	ACTASE	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Italy	J.C. HEALTHCARE srl Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	Risperidone	ACTASE	1 mg	Film coated tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Italy	J.C. HEALTHCARE srl Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	Risperidone	ACTASE	2 mg	Film coated tablet	Oral use	
Italy	J.C. HEALTHCARE srl Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	Risperidone	ACTASE	3 mg	Film coated tablet	Oral use	
Italy	J.C. HEALTHCARE srl Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	Risperidone	ACTASE	4 mg	Film coated tablet	Oral use	
Latvia	UAB Johnson &Johnson Šeimyniškių g.1A LT-09312 Vilnius Lithuania	Risperidone	Rispolept	1 mg	Tablets	Oral use	
Latvia	UAB Johnson &Johnson, Šeimyniškių g.1A, LT-09312 Vilnius, Lithuania	Risperidone	Rispolept	2 mg	Tablets	Oral use	
Latvia	UAB Johnson&Johnson, Šeimyniškių g.1A, Vilnius, Lithuania	Risperidone	Rispolept	3 mg	Tablets	Oral use	
Latvia	UAB Johnson&Johnson, Šeimyniškių g.1A, LT-09312 Vilnius, Lithuania	Risperidone	Rispolept	4 mg	Tablets	Oral use	
Latvia	UAB Johnson&Johnson, Šeimyniškių g.1A, LT-09312	Risperidone	Rispolept	1 mg	Oral solution	Oral use	1 mg/ 1 ml

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	Vilnius, Lithuania						
Latvia	UAB Johnson & Johnson, Šeimyniškių g. 1A, LT-09312 Vilnius, Lithuania	Risperidone	Risperdal Quicklet	1 mg	Orodispersible tablets	Oral use	
Latvia	UAB Johnson & Johnson, Šeimyniškių g. 1A, LT-09312 Vilnius, Lithuania	Risperidone	Risperdal Quicklet	2 mg	Orodispersible tablets	Oral use	
Latvia	UAB Johnson & Johnson, Šeimyniškių g.1A, LT-09312 Vilnius, Lithuania	Risperidone	Risperdal Quicklet	4 mg	Orodispersible tablets	Oral use	
Lithuania	UAB „Johnson & Johnson“, Šeimyniškių g. 1A, LT-09312 Vilnius, Lithuania	Risperidone	Rispolept	1 mg	Film-coated tablets	Oral use	
Lithuania	UAB „Johnson & Johnson“, Šeimyniškių g. 1A, LT-09312 Vilnius, Lithuania	Risperidone	Rispolept	2 mg	Film-coated tablets	Oral use	
Lithuania	UAB „Johnson & Johnson“, Šeimyniškių g. 1A, LT-09312 Vilnius, Lithuania	Risperidone	Rispolept	3 mg	Film-coated tablets	Oral use	
Lithuania	UAB „Johnson & Johnson“, Šeimyniškių g. 1A, LT-09312 Vilnius, Lithuania	Risperidone	Rispolept	4 mg	Film-coated tablets	Oral use	
Lithuania	UAB „Johnson & Johnson“, Šeimyniškių g. 1A, LT-09312 Vilnius, Lithuania	Risperidone	Rispolept	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Lithuania	UAB „Johnson & Johnson“, Šeimyniškių g. 1A, LT-09312 Vilnius, Lithuania	Risperidone	Rispolept Quicklet	1 mg	Orodispersible tablets	Oral use	
Lithuania	UAB „Johnson & Johnson“, Šeimyniškių g. 1A, LT-09312 Vilnius, Lithuania	Risperidone	Rispolept Quicklet	2 mg	Orodispersible tablets	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem Belgium	Risperidone	Risperidone J-C Instasolv	0.5 mg	Orodispersible tablet	Oral use	
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem, Belgium	Risperidone	Risperdal	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem, Belgium	Risperidone	Risperdal	0.5 mg	Film-coated tablet	Oral use	
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem, Belgium	Risperidone	Risperdal	1 mg	Film-coated tablet	Oral use	
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem, Belgium	Risperidone	Risperdal	2 mg	Film-coated tablet	Oral use	
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem, Belgium	Risperidone	Risperdal	3 mg	Film-coated tablet	Oral use	
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem, Belgium	Risperidone	Risperdal	4 mg	Film-coated tablet	Oral use	
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem, Belgium	Risperidone	Risperdal	6 mg	Film-coated tablet	Oral use	
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem, Belgium	Risperidone	Risperdal Instasolv	0.5 mg	Orodispersible tablet	Oral use	
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem, Belgium	Risperidone	Risperdal Instasolv	1 mg	Orodispersible tablet	Oral use	
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem,	Risperidone	Risperdal Instasolv	2 mg	Orodispersible tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	Belgium						
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem, Belgium	Risperidone	Risperidone J-C	0.5 mg	Film-coated tablet	Oral use	
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem, Belgium	Risperidone	Risperidone J-C	1 mg	Film-coated tablet	Oral use	
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem, Belgium	Risperidone	Risperidone J-C	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem, Belgium	Risperidone	Risperidone J-C	2 mg	Film-coated tablet	Oral use	
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem, Belgium	Risperidone	Risperidone J-C	3 mg	Film-coated tablet	Oral use	
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem, Belgium	Risperidone	Risperidone J-C	4 mg	Film-coated tablet	Oral use	
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem, Belgium	Risperidone	Risperidone J-C	6 mg	Film-coated tablet	Oral use	
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem, Belgium	Risperidone	Risperidone J-C Instasolv	1 mg	Orodispersible tablet	Oral use	
Luxemburg	Janssen Cilag N.V. Roderveldlaan 1 2600 Berchem, Belgium	Risperidone	Risperidone J-C Instasolv	2 mg	Orodispersible tablet	Oral use	
Malta	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse Belgium	Risperidone	Risperdal	1mg	Tablets	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Malta	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse Belgium	Risperidone	Risperdal	2 mg	Tablets	Oral use	
Malta	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse Belgium	Risperidone	Risperdal	3 mg	Tablets	Oral use	
Malta	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse Belgium	Risperidone	Risperdal	1 mg	Oral Solution	Oral use	1 mg/ 1 ml
Malta	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse Belgium	Risperidone	Risperdal Quicklets	0.5mg	Orodispersible tablets	Oral use	
Malta	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse Belgium	Risperidone	Risperdal Quicklets	1 mg	Orodispersible tablets	Oral use	
Malta	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse Belgium	Risperidone	Risperdal Quicklets	2 mg	Orodispersible tablets	Oral use	
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Risperidon	Risperdal Risperdal omhulde tabletten 0,5 mg	0.5 mg	Filmcoated talbets	Oral use	
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg	Risperidon	Risperdal Risperdal omhulde tabletten 1 mg	1 mg	Filmcoated tablets	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	The Netherlands						
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Risperidon	Risperdal Risperdal omhulde tabletten 2 mg	2 mg	Filmcoated tablets	Oral use	
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Risperidon	Risperdal Risperdal omhulde tabletten 3 mg	3 mg	Filmcoated tablets	Oral use	
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Risperidon	Risperdal Risperdal omhulde tabletten 4 mg	4 mg	Filmcoated tablets	Oral use	
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Risperidon	Risperdal Risperdal omhulde tabletten 6 mg	6 mg	Filmcoated tablets	Oral use	
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Risperidon	Risperdal Risperdal omhulde tabletten 8 mg	8 mg	Filmcoated tablets	Oral use	
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Risperidon	Belivon Belivon omhulde tabletten 1 mg	1 mg	Filmcoated tablets	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Risperidon	Belivon Belivon omhulde tabletten 2 mg	2 mg	Filmcoated tablets	Oral use	
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Risperidon	Belivon Belivon omhulde tabletten 3 mg	3 mg	Filmcoated tablets	Oral use	
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Risperidon	Belivon	4 mg	Filmcoated tablets	Oral use	
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Risperidon	Risperdal Risperdal 1 mg/ml, drank	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Risperidon	Belivon Belivon 1 mg/ml	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Risperidon	Risperdal Quicklet Risperdal Quicklet 0,5 mg	0.5 mg	Orodisperable tablet	Oral use	
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 PO Box 90240	Risperidon	Risperdal Quicklet Risperdal Quicklet 1 mg	1 mg	Orodisperable tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	5000 LT Tilburg The Netherlands						
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Risperidon	Risperdal Quicklet Risperdal Quicklet 2 mg	2 mg	Orodisperable tablet	Oral use	
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Risperidon	Risperdal Quicklet Risperdal Quicklet 3 mg	3 mg	Orodisperable tablet	Oral use	
Netherlands	Janssen-Cilag B.V. Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Risperidon	Risperdal Quicklet Risperdal Quicklet 4 mg	4 mg	Orodisperable tablet	Oral use	
Norway	Janssen-Cilag AS Hoffsveien 1D 0275 Oslo Norway	Risperidone	Belivon	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Norway	Janssen-Cilag AS Hoffsveien 1D 0275 Oslo Norway	Risperidone	Belivon	1 mg	Film-coated tablet	Oral use	
Norway	Janssen-Cilag AS Hoffsveien 1D 0275 Oslo Norway	Risperidone	Belivon	2 mg	Film-coated tablet	Oral use	
Norway	Janssen-Cilag AS Hoffsveien 1D 0275 Oslo Norway	Risperidone	Belivon	3 mg	Film-coated tablet	Oral use	
Norway	Janssen-Cilag AS Hoffsveien 1D	Risperidone	Belivon	4 mg	Film-coated tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	0275 Oslo Norway						
Norway	Janssen-Cilag AS Hoffsveien 1D 0275 Oslo Norway	Risperidone	Risperdal	0,5 mg	Orodispersible tablet	Oral use	
Norway	Janssen-Cilag AS Hoffsveien 1D 0275 Oslo Norway	Risperidone	Risperdal	1 mg	Orodispersible tablet	Oral use	
Norway	Janssen-Cilag AS Hoffsveien 1D 0275 Oslo Norway	Risperidone	Risperdal	2 mg	Orodispersible tablet	Oral use	
Norway	Janssen-Cilag AS Hoffsveien 1D 0275 Oslo Norway	Risperidone	Risperdal	3 mg	Orodispersible tablet	Oral use	
Norway	Janssen-Cilag AS Hoffsveien 1D 0275 Oslo Norway	Risperidone	Risperdal	4 mg	Orodispersible tablet	Oral use	
Norway	Janssen-Cilag AS Hoffsveien 1D 0275 Oslo Norway	Risperidone	Risperdal	0,5 mg	Film-coated tablet	Oral use	
Norway	Janssen-Cilag AS Hoffsveien 1D 0275 Oslo Norway	Risperidone	Risperdal	1 mg	Film-coated tablet	Oral use	
Norway	Janssen-Cilag AS Hoffsveien 1D 0275 Oslo Norway	Risperidone	Risperdal	2 mg	Film-coated tablet	Oral use	
Norway	Janssen-Cilag AS Hoffsveien 1D 0275 Oslo Norway	Risperidone	Risperdal	3 mg	Film-coated tablet	Oral use	
Norway	Janssen-Cilag AS Hoffsveien 1D 0275 Oslo Norway	Risperidone	Risperdal	4 mg	Film-coated tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Norway	Janssen-Cilag AS Hoffsveien 1D 0275 Oslo Norway	Risperidone	Risperdal	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Poland	Janssen-Cilag International N.V. Turnhauseveg 30 B-2340 Beerse Belgium	Risperidone	Rispolept	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Poland	Janssen-Cilag International N.V. Turnhauseveg 30 B-2340 Beerse Belgium	Risperidone	Rispolept	1 mg	Film-coated tablet	Oral use	
Poland	Janssen-Cilag International N.V. Turnhauseveg 30 B-2340 Beerse Belgium	Risperidone	Rispolept	2 mg	Film-coated tablet	Oral use	
Poland	Janssen-Cilag International N.V. Turnhauseveg 30 B-2340 Beerse Belgium	Risperidone	Rispolept	3 mg	Film-coated tablet	Oral use	
Poland	Janssen-Cilag International N.V. Turnhauseveg 30 B-2340 Beerse Belgium	Risperidone	Rispolept	4 mg	Film-coated tablet	Oral use	
Poland	Janssen-Cilag International N.V. Turnhauseveg 30 B-2340 Beerse Belgium	Risperidone	Rispolept Quicklet	0,5 mg	Orodispersible tablet	Oral use	
Poland	Janssen-Cilag International N.V. Turnhauseveg 30 B-2340 Beerse Belgium	Risperidone	Rispolept Quicklet	1 mg	Orodispersible tablet	Oral use	
Poland	Janssen-Cilag International N.V. Turnhauseveg 30	Risperidone	Rispolept Quicklet	2 mg	Orodispersible tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	B-2340 Beerse Belgium						
Poland	Janssen-Cilag International N.V. Turnhauseveg 30 B-2340 Beerse Belgium	Risperidone	Rispolept Quicklet	3 mg	Orodispersible tablet	Oral use	
Poland	Janssen-Cilag International N.V. Turnhauseveg 30 B-2340 Beerse Belgium	Risperidone	Rispolept Quicklet	4 mg	Orodispersible tablet	Oral use	
Portugal	Janssen Farmacêutica Portugal Lda. Estrada Consiglieri Pedroso 69 A - Queluz de Baixo 2734-503 Barcarena Portugal	Risperidona	Risperdal	1 mg	Film-coated tablet	Oral use	
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo 2734-503 Barcarena Portugal	Risperidona	Risperdal	2 mg	Film-coated tablet	Oral use	
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo 2734-503 Barcarena Portugal	Risperidona	Risperdal	3 mg	Film-coated tablet	Oral use	
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo 2734-503 Barcarena Portugal	Risperidona	Risperdal	4 mg	Film-coated tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo 2734-503 Barcarena Portugal	Risperidona	Risperdal	1 mg	Oral solution	Oral use	
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo 2734-503 Barcarena Portugal	Risperidona	Risperdal	0.25 mg	Film-coated tablet	Oral use	
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo 2734-503 Barcarena Portugal	Risperidona	Risperdal	0.5 mg	Film-coated tablet	Oral use	
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo 2734-503 Barcarena Portugal	Risperidona	Risperdal Quicklet	0.5 mg	Orodispersible tablet	Oral use	
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo 2734-503 Barcarena Portugal	Risperidona	Risperdal Quicklet	1 mg	Orodispersible tablet	Oral use	
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo 2734-503 Barcarena Portugal	Risperidona	Risperdal Quicklet	2 mg	Orodispersible tablet	Oral use	
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69	Risperidona	Risperdal Quicklet	3 mg	Orodispersible tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	A - Queluz de Baixo 2734-503 Barcarena Portugal						
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo 2734-503 Barcarena Portugal	Risperidona	Risperdal Quicklet	4 mg	Orodispersible tablet	Oral use	
Romania	Janssen Pharmaceutica N.V. Turnhoutseweg 30 2340 Beerse Belgium	Risperidone	Rispolept 1 mg	1 mg	Film-coated tablets	Oral use	
Romania	Janssen Pharmaceutica N.V. Turnhoutseweg 30 2340 Beerse Belgium	Risperidone	Rispolept 2 mg	2 mg	Film-coated tablets	Oral use	
Romania	Janssen Pharmaceutica N.V. Turnhoutseweg 30, 2340 Beerse, Belgium	Risperidone	Rispolept 3 mg	3 mg	Film-coated tablets	Oral use	
Romania	Janssen Pharmaceutica N.V. Turnhoutseweg 30, 2340 Beerse, Belgium	Risperidone	Rispolept 4 mg	4 mg	Film-coated tablets	Oral use	
Romania	Janssen Pharmaceutica N.V. Turnhoutseweg 30, 2340 Beerse, Belgium	Risperidone	Rispolept	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Romania	Janssen Pharmaceutica N.V. Turnhoutseweg 30, 2340 Beerse, Belgium	Risperidone	Rispolept Quicklet	1 mg	Dispersible tablets	Oral use	
Romania	Janssen Pharmaceutica N.V. Turnhoutseweg 30, 2340 Beerse, Belgium	Risperidone	Rispolept Quicklet	2 mg	Dispersible tablets	Oral use	
Slovak Republic	Johnson & Johnson s.r.o. Plynárenská 7/B 824 78 Bratislava	Risperidone	Risperdal	1 mg	Film coated tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	Slovak Republic						
Slovak Republic	Johnson & Johnson s.r.o. Plynárenská 7/B 824 78 Bratislava Slovak Republic	Risperidone	Risperdal	2 mg	Film coated tablet	Oral use	
Slovak Republic	Johnson & Johnson s.r.o. Plynárenská 7/B 824 78 Bratislava Slovak Republic	Risperidone	Risperdal	3 mg	Film coated tablet	Oral use	
Slovak Republic	Johnson & Johnson s.r.o. Plynárenská 7/B 824 78 Bratislava Slovak Republic	Risperidone	Risperdal	4 mg	Film coated tablet	Oral use	
Slovak Republic	Johnson & Johnson s.r.o. Plynárenská 7/B 824 78 Bratislava Slovak Republic	Risperidone	Risperdal	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Slovak Republic	Johnson & Johnson s.r.o. Plynárenská 7/B 824 78 Bratislava Slovak Republic	Risperidone	Risperdal Quicklet	1 mg	Orodispersible tablet	Oral use	
Slovak Republic	Johnson & Johnson s.r.o. Plynárenská 7/B 824 78 Bratislava Slovak Republic	Risperidone	Risperdal Quicklet	2 mg	Orodispersible tablet	Oral use	
Slovak Republic	Johnson & Johnson s.r.o. Plynárenská 7/B 824 78 Bratislava Slovak Republic	Risperidone	Risperdal Quicklet	3 mg	Orodispersible tablet	Oral use	
Slovak Republic	Johnson & Johnson s.r.o. Plynárenská 7/B 824 78 Bratislava	Risperidone	Risperdal Quicklet	4 mg	Orodispersible tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	Slovak Republic						
Slovenia	Johnson & Johnson d.o.o. Šmartinska 53 Ljubljana Slovenia	Risperidone	Risperdal 1 mg filmsko obložene tablete	1 mg	Film-coated tablets	Oral use	
Slovenia	Johnson & Johnson d.o.o., Šmartinska 53, Ljubljana, Slovenia	Risperidone	Risperdal Risperdal 2 mg filmsko obložene tablete	2 mg	Film-coated tablets	Oral use	
Slovenia	Johnson & Johnson d.o.o., Šmartinska 53, Ljubljana, Slovenia	Risperidone	Risperdal 3 mg filmsko obložene tablete	3 mg	Film-coated tablets	Oral use	
Slovenia	Johnson & Johnson d.o.o., Šmartinska 53, Ljubljana, Slovenia	Risperidone	Risperdal 4 mg filmsko obložene tablete	4 mg	Film-coated tablets	Oral use	
Slovenia	Johnson & Johnson d.o.o., Šmartinska 53, Ljubljana, Slovenia	Risperidone	Risperdal 1 mg/ml peroralna raztopina	1 mg/ml	Oral solution	Oral use	1 mg/ 1 ml
Slovenia	Johnson & Johnson d.o.o., Šmartinska 53, Ljubljana, Slovenia	Risperidone	Risperdal Quicklet 0,5 mg orodisperzibilna tableta	0,5 mg	Orodispersible tablets	Oral use	
Slovenia	Johnson & Johnson d.o.o., Šmartinska 53, Ljubljana, Slovenia	Risperidone	Risperdal Quicklet 1 mg orodisperzibilna tableta	1 mg	Orodispersible tablets	Oral use	
Slovenia	Johnson & Johnson d.o.o., Šmartinska 53, Ljubljana, Slovenia	Risperidone	Risperdal Quicklet 2 mg orodisperzibilna tableta	2 mg	Orodispersible tablets	Oral use	
Spain	Janssen Cilag, SA Paseo de las Doce Estrellas 5-7 28042 Madrid	Risperidone	Risperdal flas	3 mg	Orodispersable tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	Spain						
Spain	Janssen Cilag, SA Paseo de las Doce Estrellas, 5-7 28042 Madrid, Spain	Risperidone	Risperdal flas	4 mg	Orodispersable tablet	Oral use	
Spain	Janssen Cilag, SA Paseo de las Doce Estrellas, 5-7 28042 Madrid, Spain	Risperidone	Risperdal flas	0.5 mg	Orodispersable tablet	Oral use	
Spain	Janssen Cilag, SA Paseo de las Doce Estrellas, 5-7 28042 Madrid, Spain	Risperidone	Risperdal flas	2 mg	Orodispersable tablet	Oral use	
Spain	Janssen Cilag, SA Paseo de las DoceEstrellas, 5-7 28042 Madrid, Spain	Risperidone	Risperdal flas	1 mg	Orodispersable tablet	Oral use	
Spain	Janssen Cilag, SA Paseo de las DoceEstrellas, 5-7 28042 Madrid, Spain	Risperidone	Risperdal	1 mg	Film coated tablets	Oral use	
Spain	Janssen Cilag, SA Paseo de las Doce Estrellas, 5- 728042 Madrid, Spain	Risperidone	Risperdal	2 mg	Film coated tablets	Oral use	
Spain	Janssen Cilag, SA Paseo de las Doce Estrellas, 5-7 28042 Madrid, Spain	Risperidone	Risperdal	3 mg	Film coated tablets	Oral use	
Spain	Janssen Cilag, SA Paseo de las DoceEstrellas, 5-7 28042 Madrid, Spain	Risperidone	Risperdal	6 mg	Film coated tablets	Oral use	
Spain	Janssen Cilag, SA Paseo de las Doce Estrellas 5-7 28042 Madrid Spain	Risperidone	Risperdal	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Sweden	Janssen-Cilag AB Box 7073 192 07 Sollentuna	Risperidone	Belivon	1 mg	Film-coated tablets	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	Sverige						
Sweden	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidone	Belivon	2 mg	Film-coated tablets	Oral use	
Sweden	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidone	Belivon	3 mg	Film-coated tablets	Oral use	
Sweden	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidone	Belivon	4 mg	Film-coated tablets	Oral use	
Sweden	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidone	Belivon	6 mg	Film-coated tablets	Oral use	
Sweden	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidone	Belivon	1 mg	Oral solution	Oral use	1 mg/ 1 ml
Sweden	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidone	Risperdal	0.5mg	Film-coated tablets	Oral use	
Sweden	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidone	Risperdal	1 mg	Film-coated tablets	Oral use	
Sweden	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidone	Risperdal	2 mg	Film-coated tablets	Oral use	
Sweden	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidone	Risperdal	3 mg	Film-coated tablets	Oral use	
Sweden	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidone	Risperdal	4 mg	Film-coated tablets	Oral use	
Sweden	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidone	Risperdal	1mg	Oral solution	Oral use	1 mg/ 1 ml
Sweden	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidone	Risperdal	0,5 mg	Oral lyophilisate	Oral use	
Sweden	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidone	Risperdal	1 mg	Oral lyophilisate	Oral use	
Sweden	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidone	Risperdal	2 mg	Oral lyophilisate	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Sweden	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidone	Risperdal	3 mg	Oral lyophilisate	Oral use	
Sweden	Janssen-Cilag AB, Box 7073 192 07 Sollentuna, Sverige	Risperidone	Risperdal	4 mg	Oral lyophilisate	Oral use	
United Kingdom	Janssen-Cilag Ltd. Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal	0.25 mg	Coated Tablet	Oral use	
United Kingdom	Janssen-Cilag Ltd. Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal	0.5 mg	Coated Tablet	Oral use	
United Kingdom	Janssen-Cilag Ltd. Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal	1 mg	Coated Tablet	Oral use	
United Kingdom	Janssen-Cilag Ltd. Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal	2 mg	Coated Tablet	Oral use	
United Kingdom	Janssen-Cilag Ltd. Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal	3 mg	Coated Tablet	Oral use	
United Kingdom	Janssen-Cilag Ltd. Saunderton High Wycombe Buckinghamshire HP14 4HJ	Risperidone	Risperdal	4 mg	Coated Tablet	Oral use	

Member State	Marketing Authorisation Holder	INN	Invented Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	United Kingdom						
United Kingdom	Janssen-Cilag Ltd. Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal	6 mg	Coated Tablet	Oral use	
United Kingdom	Janssen-Cilag Ltd. Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal Liquid	1 mg	Oral solution	Oral use	1 mg/ 1 ml
United Kingdom	Janssen-Cilag Ltd. Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal Quicklet	0.5 mg	Orodispersible tablets	Oral use	
United Kingdom	Janssen-Cilag Ltd. Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal Quicklet	1 mg	Orodispersible tablets	Oral use	
United Kingdom	Janssen-Cilag Ltd. Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal Quicklet	2 mg	Orodispersible tablets	Oral use	
United Kingdom	Janssen-Cilag Ltd. Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	Risperidone	Risperdal Quicklet	3 mg	Orodispersible tablets	Oral use	
United	Janssen-Cilag Ltd.	Risperidone	Risperdal Quicklet	4mg	Orodispersible	Oral use	

Member State	**Marketing Authorisation Holder**	**INN**	**Invented Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Content (concentration)**
Kingdom	Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom				tablets		

ANNEX II

SCIENTIFIC CONCLUSIONS AND GROUNDS FOR THE AMENDMENT OF THE SUMMARIES OF PRODUCT CHARACTERISTICS, LABELLING AND PACKAGE LEAFLET PRESENTED BY THE EMEA

SCIENTIFIC CONCLUSIONS

OVERALL SUMMARY OF THE SCIENTIFIC EVALUATION OF RISPERDAL AND ASSOCIATED NAMES (SEE ANNEX I)

Risperdal (risperidone) is a benzisoxazole derivative with potent combined serotonin $5HT_{2A}$ and dopamine D_2 receptor-blocking properties. Adrenergic α_1 and, to a lesser extent, histamine H_1 and adrenergic α_2 receptors are also antagonised by risperidone. Authorised formulations of oral risperidone include oral film-coated tablets, orodispersible tablets and an oral solution.

The Referral procedure under Article 30 of Directive 2001/83/EC, as amended for Risperdal was initiated in order to resolve divergences amongst the nationally authorised Product Information texts across the EU and EEA Member States, in particular with respect to the sections on indication, posology and method of administration, contraindications, special warnings and precautions for use and interactions with other medicinal products or other forms of interactions. The CHMP assessed the proposed wording provided by the MAH, and particular attention was given to the following issues:

For the indication in Schizophrenia, the CHMP assessed the proposed dosing, and was of the opinion that although the 8 mg dose could be considered as a treatment option for particular patients with schizophrenia, treating physicians should individualise treatment and use the lowest efficacious dose for each patient with a target dose of 4 to 6 mg/day. Regarding the posology in elderly with schizophrenia, the CHMP considered that the data in elderly patients is limited but suggests that a lower starting dose with a more conservative dose titration than in younger adults is recommended and adopted the following wording:

"A starting dose of 0.5 mg twice daily is recommended. This dosage can be individually adjusted with 0.5 mg twice-daily increments to 1 to 2 mg twice daily."

For the indication in Manic episodes associated with Bipolar Disorders, the CHMP assessed the safety and efficacy of the proposed 2 mg and 3 mg starting doses and noted that no comparisons on the change in efficacy measurements in the first days of treatment were made. Therefore the CHMP was of the opinion that starting doses should be restricted to 2 mg for the first day in bipolar mania. The CHMP also assessed the optimal, recommended dose range for bipolar mania and considered, based on the submitted efficacy analysis of risperidone patients, grouped according to their mode daily dose during the study, that efficacy was demonstrated over the recommended dose range 1 to 6 mg/day, and that some patients can effectively be treated at doses in the lower end of this dose range.

The CHMP also assessed the efficacy data for bipolar mania in elderly patients. Due to the low number of patients and based on the limited data available, the CHMP did not consider it justified to treat elderly with bipolar mania with the posology recommended in adults. The CHMP concluded that the upper limit of dosage should be restricted and adopted the following dosage recommendations:

"A starting dose of 0.5 mg twice daily is recommended. This dosage can be individually adjusted with 0.5 mg twice daily increments to 1 to 2 mg twice daily. Since clinical experience in elderly is limited, caution should be exercised."

Finally, the CHMP assessed the data submitted on the use of risperidone in the treatment of mild forms of mania. Given the small number of patients with mild mania in clinical trials and the limited data available, the CHMP could not guarantee that the balance between efficacy and safety in patients with mild mania is the same as in patients with moderate to severe mania. The CHMP therefore adopted the following wording in line with the indication for other approved antipsychotics:

"*Risperdal is indicated for the treatment of moderate to severe manic episodes associated with bipolar disorders."*

For the indication in Severe Aggression in Alzheimer's Dementia the CHMP assessed the provided data on

the optimum treatment duration, in light of the need to balance the significant safety issues against the severity of symptoms in the targeted population (severe aggression). The CHMP decided to restrict the duration of the short-term therapy to 6 weeks, due to safety considerations. Regarding the qualification of "severe aggression", the CHMP considered that rating scales were not practical in clinical settings and that the most important clinical criteria to be met before treatment is initiated is that the aggression places the person or carer at risk of harm and that the behaviour is persistent. Accordingly, the following wording was adopted:

"Risperdal is indicated for the short-term treatment (up to 6 weeks) of persistent aggression in patients with moderate to severe Alzheimer's dementia unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others."

The CHMP was of the opinion that the efficacy in Alzheimer's dementia was similar compared to efficacy in vascular/ mixed dementias and that patients with severe aggression in vascular/ mixed dementias should be excluded from treatment with risperidone because of safety concerns. Restriction of the indication to patients with Alzheimer's dementia is also correct in view of efficacy. The CHMP decided to limit the indication to AD, however the CHMP amended the warning in the SPC, regarding the magnitude of the risk for CVAEs in patients with MD/VD to the following wording:

"The risk of CVAEs was significantly higher in patients with mixed or vascular type of dementia when compared to Alzheimer dementia. Therefore, patients with other types of dementias than Alzheimer's should not be treated with risperidone."

In addition, the CHMP assessed the safety and efficacy of risperidone and implemented warning and precaution texts in section 4.4 of the SPC, to address the increased risk for CVAE and the increased mortality with atypical antipsychotics in patients with dementia. Further warnings were implemented with regards to patients with mixed or vascular type of dementia and to the need for close monitoring of patients with Alzheimer's dementia. The CHMP also adopted wordings further restricting the target population and the treatment duration. In conclusion, the CHMP was of the opinion that the current weight of evidence is that the benefit-risk assessment remains favourable in this restricted target population indication of persistent aggression in Alzheimer's dementia for short-term treatment only (6 weeks) and with all restrictions and conditions indicated in the SPC.

Finally, the CHMP noted the data and the responses submitted by the MAH with regards to safety signals, both in normal and elderly patients and agreed with the revised and corrected tables on CVAEs and ADRs.

For the <u>indication in Severe Aggression in Children/Adolescents with Conduct Disorder</u>, the CHMP assessed the safety profile in children/adolescents, requesting further clarifications, especially with regards to the Contradictions and discrepancies between the actual Safety Overview (April 2008) and the previous Safety Overview (January 2008) in children/ adolescents with Disruptive Behaviour Disorder (DBD). The CHMP also assessed the consistency of the Extrapyramidal Symptoms and the evidence suggesting regression in sexual maturation. The CHMP considered that while regression of sexual maturation was not supported, the SPC states that "*the effects of long-term treatment on sexual maturation and height have not been adequately studied*" and as a consequence, the sentence "*Treatment with risperidone for up to 1 year showed no adverse effects on sexual maturation*" in section 4.4 should be deleted.

The CHMP assessed the "Relapse Prevention Study" (12 weeks of open-label and single-blind risperidone treatment followed by a 6-month double-blind) and was of the opinion that it may only be considered as supportive, due to the fact that only responders entered the double-blind phase. The two 6 week- short term studies are considered as the main efficacy studies and the treatment should be restricted to short-term treatment (6 weeks) as the safety profile in children/ adolescents appears worse than in adults.

The CHMP also discussed the use of risperidone in children with normal intellectual functioning, noting that the controlled trials are predominantly conducted in children with borderline IQ or mental retardation. According to the safety profile of risperidone in children, the population of use should not be expanded to children and adolescents with a normal IQ, since due to the structural differences between the brains of

children and adolescents with normal IQ and those with mental retardation, it cannot be assumed that the two populations would respond to antipsychotic medication in an identical manner. However, the CHMP decided to adopt an indication without restriction to specific IQ.

The CHMP further discussed efficacy in Children and Adolescents with Autistic Disorder, a Pervasive Developmental Disorder that is different from Conduct Disorder which is a Disruptive Behaviour Disorder. As a consequence, children with autistic disorders are not included in the proposed indication. This exclusion is supported by the fact that the primary symptoms of the autism disorder cannot successfully be treated with Risperdal because the target symptoms in autism for which Risperdal has demonstrated its most robust efficacy are associated symptoms rather than a broad spectrum of symptoms of the disease. Because of the lack of specificity and the availability of other treatment options, the CHMP did not consider~~ed~~ the indication in Autistic Disorder as supported. In conclusion, the CHMP adopted the following indication:

"Risperdal is indicated for the short-term symptomatic treatment (up to 6 weeks) of ~~severe~~ persistent aggression in conduct ~~or other disruptive behaviour~~ disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation diagnosed according to DSM-IV criteria, in whom the severity of aggressive or other disruptive behaviours require pharmacologic treatment. Pharmacological treatment should be an integral part of a more comprehensive treatment programme, including psychosocial and educational intervention. It is recommended that risperidone be prescribed by a specialist in child neurology and child and adolescent psychiatry or physicians well familiar with the treatment of conduct ~~Disruptive Behaviour~~ disorder of children and adolescents."

For section 4.2, the CHMP revised the wording stating that risperidone should not be recommended for use in children/ adolescents under 18 years of age with schizophrenia or with bipolar mania, due to a lack of systematic efficacy/safety and clinical data for this age group.

For section 4.4, the CHMP implemented a revised wording for the hyperprolactinaemia section, excluding specific mention of prolactinoma and breast cancer, as although data supporting a possible relationship between hyperprolactinaemia and risk of some prolactin-dependent tumours exists, the data is still largely inconclusive from a clinical perspective. A statement was included in section 4.4 on the risk in elderly patients with dementia treated concomitantly with furosemide and risperidone. The CHMP also implemented a number of revisions in the subsection on children and adolescents, in particular with regards to sedation and clinically significant weight gain.

For section 4.5, the CHMP assessed and harmonised wording on interactions with other medicinal products, discussing in particular torsades de pointes, products inhibiting the hepatic metabolism of risperidone the combination with other centrally-acting substances due to the increased risk of sedation and dopamine agonists. The CHMP also deleted the mention of haloperidol, discussed interaction with verapamil and revised the wording on plasma concentrations. The CHMP also inserted texts on the interaction of risperidone with food.

For section 4.8, the CHMP assessed and completely revised the text of the SPC, taking into account new adverse event and tightening the section by revising the grouping of terms of adverse events. Left and right bundle branch block were grouped together but sedation and somnolence, and anxiety and nervousness were ungrouped. The CHMP decided not to group the extrapyramidal symptoms within the table of section 4.8 but revised the footnote referring to parkinsonism respectively extrapyramidal in section 4.8 and inserted a footnote for hyperprolactinaemia.

As a Condition of the Marketing Authorisation, the CHMP requested the MAH to commit to generate a collection of long-term data for the evaluation of long-term safety of risperidone in children and adolescents with conduct disorder in terms of potential effects on growth (height and weight), mental development, and sexual maturation (by Tanner stage). The study should also assess prolactin values and possible prolactin-related AEs. Regarding cognitive assessment, the MAH should make a proposal as to how it would be possible to assess effects on cognitive development.

The CHMP assessed the proposal from the MAH to conduct an additional retrospective cohort study based on available medical records, in which information regarding prescription as well as Tanner staging and growth would be available. As the treatment duration is now limited, the CHMP did not consider a prospective long-term study to be required.

Finally, the CHMP noted that the Risperdal oral solution pipettes were updated in 2007 to include the graduation for each 0.25 mg with different designs depending on the size of the pipette. A number of additional revisions were made to the SPC and the revisions made to the SPC were implemented accordingly in the labelling and the package leaflet.

All sections of the SPC were thoroughly assessed and all revisions were implemented accordingly in the Labelling and in the Package Leaflet, achieving a harmonised Product Information text. Based on the available data, the CHMP is of the opinion that all raised question were adequately addressed and that the harmonised Product Information wording is acceptable.

GROUNDS FOR AMENDMENT OF THE SUMMARY OF PRODUCT CHARACTERISTICS, LABELLING AND PACKAGE LEAFLET

Whereas

- the scope of the referral was the harmonisation of the Summaries of Products Characteristics, labelling and package leaflet,

- the Summaries of Products Characteristic, labelling and package leaflet proposed by the Marketing Authorisation Holders have been assessed based on the documentation submitted and the scientific discussion within the Committee,

- the Marketing Authorisation has agreed to the commit to the Conditions of the Marketing Authorisation,

the CHMP has recommended the amendment of the Marketing Authorisations for which the Summaries of Product Characteristics, labelling and package leaflet are set out in Annex III for Risperdal and associated names (see Annex I). The conditions of the Marketing Authorisation are listed in Annex IV.

ANNEX III

SUMMARY OF PRODUCT CHARACTERISTICS,
LABELLING AND PACKAGE LEAFLET

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

RISPERDAL and associated names (see Annex I) 0.25 mg film-coated tablets
[See Annex I – To be completed nationally]

RISPERDAL and associated names (see Annex I) 0.5 mg film-coated tablets

RISPERDAL and associated names (see Annex I) 1 mg film-coated tablets

RISPERDAL and associated names (see Annex I) 2 mg film-coated tablets

RISPERDAL and associated names (see Annex I) 3 mg film-coated tablets

RISPERDAL and associated names (see Annex I) 4 mg film-coated tablets

RISPERDAL and associated names (see Annex I) 6 mg film-coated tablets

RISPERDAL Quicklet and associated names (see Annex I): 0.5 mg orodispersible tablets

RISPERDAL Quicklet and associated names (see Annex I): 1 mg orodispersible tablets

RISPERDAL Quicklet and associated names (see Annex I): 2 mg orodispersible tablets

RISPERDAL Quicklet and associated names (see Annex I): 3 mg orodispersible tablets

RISPERDAL Quicklet and associated names (see Annex I): 4 mg orodispersible tablets

RISPERDAL and associated names (see Annex I) 1mg/ml oral solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

[To be completed nationally]

3. PHARMACEUTICAL FORM

[To be completed nationally]

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

RISPERDAL is indicated for the treatment of schizophrenia.

RISPERDAL is indicated for the treatment of moderate to severe manic episodes associated with bipolar disorders.

RISPERDAL is indicated for the short-term treatment (up to 6 weeks) of persistent aggression in patients with moderate to severe Alzheimer's dementia unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others.

RISPERDAL is indicated for the short-term symptomatic treatment (up to 6 weeks) of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation diagnosed according to DSM-IV criteria, in whom the severity of

aggressive or other disruptive behaviours require pharmacologic treatment. Pharmacological treatment should be an integral part of a more comprehensive treatment programme, including psychosocial and educational intervention. It is recommended that risperidone be prescribed by a specialist in child neurology and child and adolescent psychiatry or physicians well familiar with the treatment of conduct disorder of children and adolescents.

4.2 Posology and method of administration

Schizophrenia

Adults

RISPERDAL may be given once daily or twice daily.

Patients should start with 2 mg/day risperidone. The dosage may be increased on the second day to 4 mg. Subsequently, the dosage can be maintained unchanged, or further individualised, if needed. Most patients will benefit from daily doses between 4 and 6 mg. In some patients, a slower titration phase and a lower starting and maintenance dose may be appropriate.

Doses above 10 mg/day have not demonstrated superior efficacy to lower doses and may cause increased incidence of extrapyramidal symptoms. Safety of doses above 16 mg/day has not been evaluated, and are therefore not recommended.

Elderly

A starting dose of 0.5 mg twice daily is recommended. This dosage can be individually adjusted with 0.5 mg twice daily increments to 1 to 2 mg twice daily.

Paediatric population

Risperidone is not recommended for use in children below age 18 with schizophrenia due to a lack of data on efficacy.

Manic episodes in bipolar disorder

Adults

RISPERDAL should be administered on a once daily schedule, starting with 2 mg risperidone. Dosage adjustments, if indicated, should occur at intervals of not less than 24 hours and in dosage increments of 1 mg per day. Risperidone can be administered in flexible doses over a range of 1 to 6 mg per day to optimize each patient's level of efficacy and tolerability. Daily doses over 6 mg risperidone have not been investigated in patients with manic episodes.

As with all symptomatic treatments, the continued use of RISPERDAL must be evaluated and justified on an ongoing basis.

Elderly
A starting dose of 0.5 mg twice daily is recommended. This dosage can be individually adjusted with 0.5 mg twice daily increments to 1 to 2 mg twice daily. Since clinical experience in elderly is limited, caution should be exercised.

Paediatric population

Risperidone is not recommended for use in children below age 18 with bipolar mania due to a lack of data on efficacy.

Persistent aggression in patients with moderate to severe Alzheimer's dementia

A starting dose of 0.25 mg twice daily is recommended. This dosage can be individually adjusted by increments of 0.25 mg twice daily, not more frequently than every other day, if needed. The optimum dose is 0.5 mg twice daily for most patients. Some patients, however, may benefit from doses up to 1 mg twice daily.

RISPERDAL should not be used more than 6 weeks in patients with persistent aggression in Alzheimer's dementia. During treatment, patients must be evaluated frequently and regularly, and the need for continuing treatment reassessed.

Conduct disorder

Children and adolescents from 5 to 18 years of age

For subjects ≥50 kg, a starting dose of 0.5 mg once daily is recommended. This dosage can be individually adjusted by increments of 0.5 mg once daily not more frequently than every other day, if needed. The optimum dose is 1 mg once daily for most patients. Some patients, however, may benefit from 0.5 mg once daily while others may require 1.5 mg once daily. For subjects <50 kg, a starting dose of 0.25 mg once daily is recommended. This dosage can be individually adjusted by increments of 0.25 mg once daily not more frequently than every other day, if needed. The optimum dose is 0.5 mg once daily for most patients. Some patients, however, may benefit from 0.25 mg once daily while others may require 0.75 mg once daily.

As with all symptomatic treatments, the continued use of RISPERDAL must be evaluated and justified on an ongoing basis.

RISPERDAL is not recommended in children less than 5 years of age, as there is no experience in children less than 5 years of age with this disorder.

Renal and hepatic impairment

Patients with renal impairment have less ability to eliminate the active antipsychotic fraction than in adults with normal renal function. Patients with impaired hepatic function have increases in plasma concentration of the free fraction of risperidone.

Irrespective of the indication, starting and consecutive dosing should be halved, and dose titration should be slower for patients with renal or hepatic impairment.

RISPERDAL should be used with caution in these groups of patients.

Method of administration

RISPERDAL is for oral use. Food does not affect the absorption of RISPERDAL.

Upon discontinuation, gradual withdrawal is advised. Acute withdrawal symptoms, including nausea, vomiting, sweating, and insomnia have very rarely been described after abrupt cessation of high doses of antipsychotic medicines (see section 4.8). Recurrence of psychotic symptoms may also occur, and the emergence of involuntary movement disorders (such as akathisia, dystonia and dyskinesia) has been reported.

Switching from other antipsychotics.

When medically appropriate, gradual discontinuation of the previous treatment while RISPERDAL therapy is initiated is recommended. Also, if medically appropriate, when switching patients from depot antipsychotics, initiate RISPERDAL therapy in place of the next scheduled injection. The need for continuing existing anti-Parkinson medicines should be re-evaluated periodically.

[To be completed nationally]

RISPERDAL orodispersible tablets:

Do not open the blister until ready to administer. Peel open the blister to expose the tablet. Do not push the tablet through the foil because it may break. Remove the tablet from the blister with dry hands.

Immediately place the tablet on the tongue. The tablet will begin disintegrating within seconds. Water may be used if desired.

RISPERDAL oral solution:

For instructions on handling RISPERDAL oral solution see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use

Elderly patients with dementia

Overall mortality

Elderly patients with dementia treated with atypical antipsychotics have an increased mortality compared to placebo in a meta-analysis of 17 controlled trials of atypical antipsychotics, including RISPERDAL. In placebo-controlled trials with RISPERDAL in this population, the incidence of mortality was 4.0% for RISPERDAL-treated patients compared to 3.1% for placebo-treated patients. The odds ratio (95% exact confidence interval) was 1.21 (0.7, 2.1). The mean age (range) of patients who died was 86 years (range 67-100).

Concomitant use with furosemide

In the RISPERDAL placebo-controlled trials in elderly patients with dementia, a higher incidence of mortality was observed in patients treated with furosemide plus risperidone (7.3%; mean age 89 years, range 75-97) when compared to patients treated with risperidone alone (3.1%; mean age 84 years, range 70-96) or furosemide alone (4.1%; mean age 80 years, range 67-90). The increase in mortality in patients treated with furosemide plus risperidone was observed in two of the four clinical trials. Concomitant use of risperidone with other diuretics (mainly thiazide diuretics used in low dose) was not associated with similar findings.

No pathophysiological mechanism has been identified to explain this finding, and no consistent pattern for cause of death observed. Nevertheless, caution should be exercised and the risks and benefits of this combination or co-treatment with other potent diuretics should be considered prior to the decision to use. There was no increased incidence of mortality among patients taking other diuretics as concomitant treatment with risperidone. Irrespective of treatment, dehydration was an overall risk factor for mortality and should therefore be carefully avoided in elderly patients with dementia.

Cerebrovascular Adverse Events (CVAE)

In placebo-controlled trials in elderly patients with dementia there was a significantly higher incidence (approximately 3-fold increased) of CVAEs, such as stroke (including fatalities) and transient ischaemic attack in patients treated with RISPERDAL compared with patients treated with placebo (mean age 85 years; range 73 to 97). The pooled data from six placebo-controlled studies in mainly elderly patients (>65 years of age) with dementia showed that CVAEs (serious and non-serious, combined) occurred in 3.3% (33/1009) of patients treated with risperidone and 1.2% (8/712) of patients treated with placebo. The odds ratio (95% exact confidence interval) was 2.96 (1.34, 7.50). The mechanism for this increased risk is not known. An increased risk cannot be excluded for other antipsychotics or other patient populations. RISPERDAL should be used with caution in patients with risk factors for stroke.

The risk of CVAEs was significantly higher in patients with mixed or vascular type of dementia when compared to Alzheimer's dementia. Therefore, patients with other types of dementias than Alzheimer's should not be treated with risperidone.

Physicians are advised to assess the risks and benefits of the use of RISPERDAL in elderly patients with dementia, taking into account risk predictors for stroke in the individual patient. Patients/caregivers should be cautioned to immediately report signs and symptoms of potential CVAEs such as sudden weakness or numbness in the face, arms or legs, and speech or vision problems. All treatment options should be considered without delay, including discontinuation of risperidone.

RISPERDAL should only be used short term for persistent aggression in patients with moderate to severe Alzheimer's dementia to supplement non-pharmacological approaches which have had limited or no efficacy and when there is potential risk of harm to self or others.

Patients should be reassessed regularly, and the need for continuing treatment reassessed.

Orthostatic hypotension

Due to the alpha-blocking activity of risperidone, (orthostatic) hypotension can occur, especially during the initial dose-titration period. Clinically significant hypotension has been observed postmarketing with concomitant use of risperidone and antihypertensive treatment. RISPERDAL should be used with caution in patients with known cardiovascular disease (e.g., heart failure, myocardial infarction, conduction abnormalities, dehydration, hypovolemia, or cerebrovascular disease), and the dosage should be gradually titrated as recommended (see section 4.2). A dose reduction should be considered if hypotension occurs.

Tardive dyskinesia/extrapyramidal symptoms (TD/EPS)

Medicines with dopamine receptor antagonistic properties have been associated with the induction of tardive dyskinesia characterised by rhythmical involuntary movements, predominantly of the tongue and/or face. The onset of extrapyramidal symptoms is a risk factor for tardive dyskinesia. If signs and symptoms of tardive dyskinesia appear, the discontinuation of all antipsychotics should be considered.

Neuroleptic malignant syndrome (NMS)

Neuroleptic Malignant Syndrome, characterised by hyperthermia, muscle rigidity, autonomic instability, altered consciousness and elevated serum creatine phosphokinase levels has been reported to occur with antipsychotics. Additional signs may include myoglobinuria (rhabdomyolysis) and acute renal failure. In this event, all antipsychotics, including RISPERDAL, should be discontinued.

Parkinson's disease and dementia with Lewy bodies

Physicians should weigh the risks versus the benefits when prescribing antipsychotics, including RISPERDAL, to patients with Parkinson's Disease or Dementia with Lewy Bodies (DLB). Parkinson's Disease may worsen with risperidone. Both groups may be at increased risk of Neuroleptic Malignant Syndrome as well as having an increased sensitivity to antipsychotic medicinal products; these patients were excluded from clinical trials. Manifestation of this increased sensitivity can include confusion, obtundation, postural instability with frequent falls, in addition to extrapyramidal symptoms.

Hyperglycemia

Hyperglycemia or exacerbation of pre-existing diabetes has been reported in very rare cases during treatment with RISPERDAL. Appropriate clinical monitoring is advisable in diabetic patients and in patients with risk factors for the development of diabetes mellitus.

Hyperprolactinaemia

Tissue culture studies suggest that cell growth in human breast tumours may be stimulated by prolactin. Although no clear association with the administration of antipsychotics has so far been demonstrated in clinical and epidemiological studies, caution is recommended in patients with relevant medical history. RISPERDAL should be used with caution in patients with pre-existing hyperprolactinaemia and in patients with possible prolactin-dependent tumours.

QT prolongation

QT prolongation has very rarely been reported postmarketing. As with other antipsychotics, caution should be exercised when risperidone is prescribed in patients with known cardiovascular disease, family history of QT prolongation, bradycardia, or electrolyte disturbances (hypokalaemia, hypomagnesaemia), as it may increase the risk of arrhythmogenic effects, and in concomitant use with medicines known to prolong the QT interval.

Seizures

RISPERDAL should be used cautiously in patients with a history of seizures or other conditions that potentially lower the seizure threshold.

Priapism

Priapism may occur with RISPERDAL treatment due to its alpha-adrenergic blocking effects.

Body temperature regulation

Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic medicines. Appropriate care is advised when prescribing RISPERDAL to patients who will be experiencing conditions which may contribute to an elevation in core body temperature, e.g., exercising strenuously, exposure to extreme heat, receiving concomitant treatment with anticholinergic activity, or being subject to dehydration.

Children and adolescents

Before risperidone is prescribed to a child or adolescent with conduct disorder they should be fully assessed for physical and social causes of the aggressive behaviour such as pain or inappropriate environmental demands.

The sedative effect of risperidone should be closely monitored in this population because of possible consequences on learning ability. A change in the time of administration of risperidone could improve the impact of the sedation on attention faculties of children and adolescents.

Risperidone was associated with mean increases in body weight and body mass index (BMI). Changes in height in the long-term open-label extension studies were within expected age-appropriate norms. The effect of long-term risperidone treatment on sexual maturation and height have not been adequately studied.

Because of the potential effects of prolonged hyperprolactinemia on growth and sexual maturation in children and adolescents, regular clinical evaluation of endocrinological status should be considered, including measurements of height, weight, sexual maturation, monitoring of menstrual functioning, and other potential prolactin-related effects.

During treatment with risperidone regular examination for extrapyramidal symptoms and other movement disorders should also be conducted.

For specific posology recommendations in children and adolescents see Section 4.2.

Excipients

The film-coated tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. (pertains only to the film-coated tablets)

The orodispersible tablets contain aspartame. Aspartame is a source of phenylalanine which may be harmful for people with phenylketonuria. (pertains only to the orodispersible tablets)

Contains sunset yellow (E110). May cause allergic reactions. (pertains only to the 2mg and 6 mg film-coated tablets)

4.5 Interaction with other medicinal products and other forms of interaction

As with other antipsychotics, caution is advised when prescribing risperidone with medicinal products known to prolong the QT interval, e.g., class Ia antiarrhythmics (e.g., quinidine, dysopiramide, procainamide), class III antiarrhythmics (e.g., amiodarone, sotalol), tricyclic antidepressant (i.e., amitriptyline), tetracyclic antidepressants (i.e., maprotiline), some antihistaminics, other antipsychotics, some antimalarials (i.e., chinice and mefloquine), and with medicines causing electrolyte imbalance (hypokalaemia, hypomagnesiaemia), bradycardia, or those which inhibit the hepatic metabolism of risperidone. This list is indicative and not exhaustive.

Potential for RISPERDAL to affect other medicinal products

Risperidone should be used with caution in combination with other centrally-acting substances notably including alcohol, opiates, antihistamines and benzodiazepines due to the increased risk of sedation.

RISPERDAL may antagonise the effect of levodopa and other dopamine agonists. If this combination is deemed necessary, particularly in end-stage Parkinson's disease, the lowest effective dose of each treatment should be prescribed.

Clinically significant hypotension has been observed postmarketing with concomitant use of risperidone and antihypertensive treatment.

RISPERDAL does not show a clinically relevant effect on the pharmacokinetics of lithium, valproate, digoxin or topiramate.

Potential for other medicinal products to affect RISPERDAL

Carbamazepine has been shown to decrease the plasma concentrations of the active antipsychotic fraction of risperidone. Similar effects may be observed with e.g. rifampicin, phenytoin and phenobarbital which also induce CYP 3A4 hepatic enzyme as well as P-glycoprotein. When carbamazepine or other CYP 3A4 hepatic enzyme/P-glycoprotein (P-gp) inducers are initiated or discontinued, the physician should re-evaluate the dosing of RISPERDAL.

Fluoxetine and paroxetine, CYP 2D6 inhibitors, increase the plasma concentration of risperidone, but less so of the active antipsychotic fraction. It is expected that other CYP 2D6 inhibitors, such as quinidine, may affect the plasma concentrations of risperidone in a similar way. When concomitant fluoxetine or paroxetine is initiated or discontinued, the physician should re-evaluate the dosing of RISPERDAL.

Verapamil, an inhibitor of CYP 3A4 and P-gp, increases the plasma concentration of risperidone.

Galantamine and donepezil do not show a clinically relevant effect on the pharmacokinetics of risperidone and on the active antipsychotic fraction.

Phenothiazines, tricyclic antidepressants, and some beta-blockers may increase the plasma concentrations of risperidone but not those of the active antipsychotic fraction. Amitriptyline does not affect the pharmacokinetics of risperidone or the active antipsychotic fraction. Cimetidine and ranitidine increase the bioavailability of risperidone, but only marginally that of the active antipsychotic fraction. Erythromycin, a CYP 3A4 inhibitor, does not change the pharmacokinetics of risperidone and the active antipsychotic fraction.

The combined use of psychostimulants (e.g., methylphenidate) with RISPERDAL in children and adolescents did not alter the pharmacokinetics and efficacy of RISPERDAL.

See section 4.4 regarding increased mortality in elderly patients with dementia concomitantly receiving furosemide.

Concomitant use of oral RISPERDAL with paliperidone is not recommended as paliperidone is the active metabolite of risperidone and the combination of the two may lead to additive active antipsychotic fraction exposure.

4.6 Pregnancy and lactation

Pregnancy

There are no adequate data from the use of risperidone in pregnant women. According to postmarketing data reversible extrapyramidal symptoms in the neonate were observed following the use of risperidone during the last trimester of pregnancy. Consequently newborns should be monitored carefully. Risperidone was not teratogenic in animal studies but other types of reproductive toxicity were seen (see section 5.3). The potential risk for humans is unknown. Therefore, RISPERDAL should not be used during pregnancy unless clearly necessary. If discontinuation during pregnancy is necessary, it should not be done abruptly.

Lactation

In animal studies, risperidone and 9-hydroxy-risperidone are excreted in the milk. It has been demonstrated that risperidone and 9-hydroxy-risperidone are also excreted in human breast milk in small quantities. There are no data available on adverse reactions in breast-feeding infants. Therefore, the advantage of breast-feeding should be weighed against the potential risks for the child.

4.7 Effects on ability to drive and use machines

RISPERDAL can have minor or moderate influence on the ability to drive and use machines due to potential nervous system and visual effects (see section 4.8). Therefore, patients should be advised not to drive or operate machinery until their individual susceptibility is known.

4.8 Undesirable effects

The most frequently reported adverse drug reactions (ADRs) (incidence ≥10%) are: Parkinsonism, headache, and insomnia.

The following are all the ADRs that were reported in clinical trials and postmarketing. The following terms and frequencies are applied: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000), very rare (<1/10,000), and not known (cannot be estimated from the available clinical trial data).

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Adverse Drug Reactions by System Organ Class and Frequency

Investigations	
Common	Blood prolactin increased[a], Weight increased
Uncommon	Electrocardiogram QT prolonged, Electrocardiogram abnormal, Blood glucose increased, Transaminases increased, White blood cell count decreased Body temperature increased, Eosinophil count increased, Haemoglobin decreased, Blood creatine phosphokinase increased
Rare	Body temperature decreased
Cardiac disorders	
Common	Tachycardia
Uncommon	Atrioventricular block, Bundle branch block, Atrial fibrillation, Sinus bradycardia, Palpitations
Blood and lymphatic system disorders	
Uncommon	Anaemia, Thrombocytopenia
Rare	Granulocytopenia
Not known	Agranulocytosis
Nervous system disorders	
Very common	Parkinsonism[b], Headache
Common	Akathisia[b], Dizziness, Tremor[b], Dystonia[b], Somnolence, Sedation, Lethargy, Dyskinesia[b]
Uncommon	Unresponsive to stimuli, Loss of consciousness, Syncope, Depressed level of consciousness, Cerebrovascular accident, Transient ischaemic attack, Dysarthria, Disturbance in attention, Hypersomnia, Dizziness postural, Balance disorder, Tardive dyskinesia, Speech disorder, Coordination abnormal, Hypoaesthesia
Rare	Neuroleptic malignant syndrome, Diabetic coma, Cerebrovascular disorder, Cerebral ischaemia, Movement disorder
Eye disorders	
Common	Vision blurred
Uncommon	Conjunctivitis, Ocular hyperaemia, Eye discharge, Eye swelling, Dry eye, Lacrimation increased, Photophobia
Rare	Visual acuity reduced, Eye rolling, Glaucoma
Ear and labyrinth disorders	
Uncommon	Ear pain, Tinnitus
Respiratory, thoracic and mediastinal disorders	
Common	Dyspnoea, Epistaxis, Cough, Nasal congestion, Pharyngolaryngeal pain

Uncommon	Wheezing, Pneumonia aspiration, Pulmonary congestion, Respiratory disorder, Rales, Respiratory tract congestion, Dysphonia
Rare	Sleep apnea syndrome, Hyperventilation
Gastrointestinal disorders	
Common	Vomiting, Diarrhoea, Constipation, Nausea, Abdominal pain, Dyspepsia, Dry mouth, Stomach discomfort
Uncommon	Dysphagia, Gastritis, Faecal incontinence, Faecaloma
Rare	Intestinal obstruction, Pancreatitis, Lip swelling, Cheilitis
Renal and urinary disorders	
Common	Enuresis
Uncommon	Dysuria, Urinary incontinence, Pollakiuria
Skin and subcutaneous tissue disorders	
Common	Rash, Erythema
Uncommon	Angioedema, Skin lesion, Skin disorder, Pruritus, Acne, Skin discolouration, Alopecia, Seborrhoeic dermatitis, Dry skin, Hyperkeratosis
Rare	Dandruff
Musculoskeletal and connective tissue disorders	
Common	Arthralgia, Back pain, Pain in extremity
Uncommon	Muscular weakness, Myalgia, Neck pain, Joint swelling, Posture abnormal, Joint stiffness, Musculoskeletal chest pain
Rare	Rhabdomyolysis
Endocrine disorders	
Rare	Inappropriate antidiuretic hormone secretion
Metabolism and nutrition disorders	
Common	Increased appetite, Decreased appetite
Uncommon	Anorexia, Polydipsia
Very rare	Diabetic ketoacidosis
Not known	Water intoxication
Infections and infestations	
Common	Pneumonia, Influenza, Bronchitis, Upper respiratory tract infection, Urinary tract infection
Uncommon	Sinusitis, Viral infection, Ear infection, Tonsillitis, Cellulitis, Otitis media, Eye infection, Localised infection, Acarodermatitis, Respiratory tract infection, Cystitis, Onychomycosis
Rare	Otitis media chronic
Vascular disorders	
Uncommon	Hypotension, Orthostatic hypotension, Flushing
General disorders and administration site conditions	
Common	Pyrexia, Fatigue, Peripheral oedema, Asthenia, Chest pain
Uncommon	Face oedema, Gait disturbance, Feeling abnormal, Sluggishness, Influenza like illness, Thirst, Chest discomfort, Chills
Rare	Generalised oedema, Hypothermia, Drug withdrawal syndrome, Peripheral coldness
Immune system disorders	
Uncommon	Hypersensitivity
Rare	Drug hypersensitivity
Not known	Anaphylactic reaction
Hepatobiliary disorders	
Rare	Jaundice
Reproductive system and breast disorders	
Uncommon	Amenorrhoea, Sexual dysfunction, Erectile dysfunction, Ejaculation disorder, Galactorrhoea, Gynaecomastia, Menstrual disorder, Vaginal discharge,
Not known	Priapism
Psychiatric disorders	

Very common	Insomnia
Common	Anxiety, Agitation, Sleep disorder
Uncommon	Confusional state, Mania, Libido decreased, Listless, Nervousness
Rare	Anorgasmia, Blunted affect

[a] Hyperprolactinemia can in some cases lead to gynaecomastia, menstrual disturbances, amenorrhoea, galactorrhea.

[b] Extrapyramidal disorder may occur: Parkinsonism (salivary hypersecretion, musculoskeletal stiffness, parkinsonism, drooling, cogwheel rigidity, bradykinesia, hypokinesia, masked facies, muscle tightness, akinesia, nuchal rigidity, muscle rigidity, parkinsonian gait, and glabellar reflex abnormal),akathisia (akathisia, restlessness, hyperkinesia, and restless leg syndrome), tremor, dyskinesia (dyskinesia, muscle twitching, choreoathetosis, athetosis, and myoclonus), dystonia.
Dystonia includes dystonia, muscle spasms, hypertonia, torticollis, muscle contractions involuntary, muscle contracture, blepharospasm, oculogyration, tongue paralysis, facial spasm, laryngospasm, myotonia, opisthotonus, oropharyngeal spasm, pleurothotonus, tongue spasm, and trismus. Tremor includes tremor and parkinsonian rest tremor. It should be noted that a broader spectrum of symptoms are included, that do not necessarily have an extrapyramidal origin.

The following is a list of additional ADRs associated with risperidone that have been identified as ADRs during clinical trials investigating the long-acting injectable risperidone formulation (RISPERDAL CONSTA) but were not determined to be ADRs in the clinical trials investigating oral RISPERDAL. This table excludes those ADRs specifically associated with the formulation or injection route of administration of RISPERDAL CONSTA.

Additional Adverse Drug Reactions Reported With RISPERDAL CONSTA but Not With Oral RISPERDAL by System Organ Class
Investigations
Weight decreased, Gamma-glutamyltransferase increased, Hepatic enzyme increased
Cardiac Disorders
Bradycardia
Blood and Lymphatic Disorders
Neutropenia
Nervous System Disorders
Paresthesia, Convulsion
Eye Disorders
Blepharospasm
Ear and Labyrinth Disorders
Vertigo
Gastrointestinal Disorders
Toothache, Tongue spasm
Skin and Subcutaneous Tissue Disorders
Eczema
Musculoskeletal, Connective Tissue, and Bone Disorders
Buttock pain
Infections and Infestations
Lower respiratory tract infection, Infection, Gastroenteritis, Subcutaneous abscess
Injury and Poisoning
Fall
Vascular Disorders
Hypertension
General Disorders and Administration Site Conditions
Pain
Psychiatric Disorders
Depression

Class effects

As with other antipsychotics, very rare cases of QT prolongation have been reported postmarketing with risperidone. Other class-related cardiac effects reported with antipsychotics which prolong QT interval include ventricular arrhythmia, ventricular fibrillation, ventricular tachycardia, sudden death, cardiac arrest and Torsades de Pointes.

Weight gain

The proportions of RISPERDAL and placebo-treated adult patients with schizophrenia meeting a weight gain criterion of ≥ 7% of body weight were compared in a pool of 6- to 8-week, placebo-controlled trials, revealing a statistically significantly greater incidence of weight gain for RISPERDAL (18%) compared to placebo (9%). In a pool of placebo-controlled 3-week studies in adult patients with acute mania, the incidence of weight increase of ≥ 7% at endpoint was comparable in the RISPERDAL (2.5%) and placebo (2.4%) groups, and was slightly higher in the active-control group (3.5%).

In a population of children and adolescents with conduct and other disruptive behaviour disorders, in long-term studies, weight increased by a mean of 7.3 kg after 12 months of treatment. The expected weight gain for normal children between 5-12 years of age is 3 to 5 kg per year. From 12-16 years of age, this magnitude of gaining 3 to 5 kg per year is maintained for girls, while boys gain approximately 5 kg per year.

Additional information on special populations

Adverse drug reactions that were reported with higher incidence in elderly patients with dementia or paediatric patients than in adult populations are described below:

Elderly patients with dementia

Transient ischaemic attack and cerebrovascular accident were ADRs reported in clinical trials with a frequency of 1.4% and 1.5%, respectively, in elderly patients with dementia. In addition, the following ADRs were reported with a frequency ≥5% in elderly patients with dementia and with at least twice the frequency seen in other adult populations: urinary tract infection, peripheral oedema, lethargy, and cough.

Paediatric patients

The following ADRs were reported with a frequency ≥5% in paediatric patients (5 to 17 years) and with at least twice the frequency seen in clinical trials in adults: somnolence/sedation, fatigue, headache, increased appetite, vomiting, upper respiratory tract infection, nasal congestion, abdominal pain, dizziness, cough, pyrexia, tremor, diarrhoea, and enuresis.

4.9 Overdose

Symptoms

In general, reported signs and symptoms have been those resulting from an exaggeration of the known pharmacological effects of risperidone. These include drowsiness and sedation, tachycardia and hypotension, and extrapyramidal symptoms. In overdose, QT-prolongation and convulsions have been reported. Torsade de Pointes has been reported in association with combined overdose of RISPERDAL and paroxetine.

In case of acute overdose, the possibility of multiple drug involvement should be considered.

Treatment

Establish and maintain a clear airway and ensure adequate oxygenation and ventilation. Gastric lavage (after intubation, if the patient is unconscious) and administration of activated charcoal together with a laxative

should be considered only when drug intake was less than one hour before. Cardiovascular monitoring should commence immediately and should include continuous electrocardiographic monitoring to detect possible arrhythmias.

There is no specific antidote to RISPERDAL. Therefore, appropriate supportive measures should be instituted. Hypotension and circulatory collapse should be treated with appropriate measures such as intravenous fluids and/or sympathomimetic agents. In case of severe extrapyramidal symptoms, an anticholinergic medicinal product should be administered. Close medical supervision and monitoring should continue until the patient recovers.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other antipsychotics, ATC code: N05AX08

Mechanism of action

Risperidone is a selective monoaminergic antagonist with unique properties. It has a high affinity for serotoninergic 5-HT_2 and dopaminergic D_2 receptors. Risperidone binds also to $alpha_1$-adrenergic receptors, and, with lower affinity, to H_1-histaminergic and $alpha_2$-adrenergic receptors. Risperidone has no affinity for cholinergic receptors. Although risperidone is a potent D_2 antagonist, which is considered to improve the positive symptoms of schizophrenia, it causes less depression of motor activity and induction of catalepsy than classical antipsychotics. Balanced central serotonin and dopamine antagonism may reduce extrapyramidal side effect liability and extend the therapeutic activity to the negative and affective symptoms of schizophrenia.

Pharmacodynamic effects

Schizophrenia

The efficacy of risperidone in the short-term treatment of schizophrenia was established in four studies, 4- to 8-weeks in duration, which enrolled over 2500 patients who met DSM-IV criteria for schizophrenia. In a 6-week, placebo-controlled trial involving titration of risperidone in doses up to 10 mg/day administered twice daily, risperidone was superior to placebo on the Brief Psychiatric Rating Scale (BPRS) total score. In an 8-week, placebo-controlled trial involving four fixed doses of risperidone (2, 6, 10, and 16 mg/day, administered twice daily), all four risperidone groups were superior to placebo on the Positive and Negative Syndrome Scale (PANSS) total score. In an 8-week, dose comparison trial involving five fixed doses of risperidone (1, 4, 8, 12, and 16 mg/day administered twice-daily), the 4, 8, and 16 mg/day risperidone dose groups were superior to the 1 mg risperidone dose group on PANSS total score. In a 4-week, placebo-controlled dose comparison trial involving two fixed doses of risperidone (4 and 8 mg/day administered once daily), both risperidone dose groups were superior to placebo on several PANSS measures, including total PANSS and a response measure (>20% reduction in PANSS total score). In a longer-term trial, adult outpatients predominantly meeting DSM-IV criteria for schizophrenia and who had been clinically stable for at least 4 weeks on an antipsychotic medicinal product were randomised to risperidone 2 to 8 mg/day or to haloperidol for 1 to 2 years of observation for relapse. Patients receiving risperidone experienced a significantly longer time to relapse over this time period compared to those receiving haloperidol.

Manic episodes in bipolar disorder

The efficacy of risperidone monotherapy in the acute treatment of manic episodes associated with bipolar I disorder was demonstrated in three double-blind, placebo-controlled monotherapy studies in approximately 820 patients who had bipolar I disorder, based on DSM-IV criteria. In the three studies, risperidone 1 to 6 mg/day (starting dose 3 mg in two studies and 2 mg in one study) was shown to be significantly superior to placebo on the pre-specified primary endpoint, i.e., the change from baseline in total Young Mania Rating

Scale (YMRS) score at Week 3. Secondary efficacy outcomes were generally consistent with the primary outcome. The percentage of patients with a decrease of ≥ 50% in total YMRS score from baseline to the 3-week endpoint was significantly higher for risperidone than for placebo. One of the three studies included a haloperidol arm and a 9-week double-blind maintenance phase. Efficacy was maintained throughout the 9-week maintenance treatment period. Change from baseline in total YMRS showed continued improvement and was comparable between risperidone and haloperidol at Week 12.

The efficacy of risperidone in addition to mood stabilisers in the treatment of acute mania was demonstrated in one of two 3-week double-blind studies in approximately 300 patients who met the DSM-IV criteria for bipolar I disorder. In one 3-week study, risperidone 1 to 6 mg/day starting at 2 mg/day in addition to lithium or valproate was superior to lithium or valproate alone on the pre-specified primary endpoint, i.e., the change from baseline in YMRS total score at Week 3. In a second 3-week study, risperidone 1 to 6 mg/day starting at 2 mg/day, combined with lithium, valproate, or carbamazepine was not superior to lithium, valproate, or carbamazepine alone in the reduction of YMRS total score. A possible explanation for the failure of this study was induction of risperidone and 9-hydroxy-risperidone clearance by carbamazepine, leading to subtherapeutic levels of risperidone and 9-hydroxy-risperidone. When the carbamazepine group was excluded in a post-hoc analysis, risperidone combined with lithium or valproate was superior to lithium or valproate alone in the reduction of YMRS total score.

Persistent aggression in dementia

The efficacy of risperidone in the treatment of Behavioural and Psychological Symptoms of Dementia (BPSD), which includes behavioural disturbances, such as aggressiveness, agitation, psychosis, activity, and affective disturbances was demonstrated in three double-blind, placebo-controlled studies in 1150 elderly patients with moderate to severe dementia. One study included fixed risperidone doses of 0.5, 1, and 2 mg/day. Two flexible-dose studies included risperidone dose groups in the range of 0.5 to 4 mg/day and 0.5 to 2 mg/day, respectively. Risperidone showed statistically significant and clinically important effectiveness in treating aggression and less consistently in treating agitation and psychosis in elderly dementia patients (as measured by the Behavioural Pathology in Alzheimer's Disease Rating Scale [BEHAVE-AD] and the Cohen-Mansfield Agitation Inventory [CMAI]). The treatment effect of risperidone was independent of Mini-Mental State Examination (MMSE) score (and consequently of the severity of dementia); of sedative properties of risperidone; of the presence or absence of psychosis; and of the type of dementia, Alzheimer's, vascular, or mixed. (See also section 4.4)

Conduct disorder

The efficacy of risperidone in the short-term treatment of disruptive behaviours was demonstrated in two double-blind placebo-controlled studies in approximately 240 patients 5 to 12 years of age with a DSM-IV diagnosis of disruptive behaviour disorders (DBD) and borderline intellectual functioning or mild or moderate mental retardation/learning disorder. In the two studies, risperidone 0.02 to 0.06 mg/kg/day was significantly superior to placebo on the pre-specified primary endpoint, i.e., the change from baseline in the Conduct Problem subscale of the Nisonger-Child Behaviour Rating Form (N-CBRF) at Week 6.

5.2 Pharmacokinetic properties

RISPERDAL orodispersible tablets and oral solution are bio-equivalent to RISPERDAL film-coated tablets. Risperidone is metabolised to 9-hydroxy-risperidone, which has a similar pharmacological activity to risperidone (see *Biotransformation and Elimination*).

Absorption

Risperidone is completely absorbed after oral administration, reaching peak plasma concentrations within 1 to 2 hours. The absolute oral bioavailability of risperidone is 70% (CV=25%). The relative oral bioavailability of risperidone from a tablet is 94% (CV=10%) compared with a solution. The absorption is not affected by food and thus risperidone can be given with or without meals. Steady-state of risperidone is reached within 1 day in most patients. Steady-state of 9-hydroxy-risperidone is reached within 4-5 days of dosing.

Distribution

Risperidone is rapidly distributed. The volume of distribution is 1-2 l/kg. In plasma, risperidone is bound to albumin and $alpha_1$-acid glycoprotein. The plasma protein binding of risperidone is 90%, that of 9-hydroxy-risperidone is 77%.

Biotransformation and elimination

Risperidone is metabolised by CYP 2D6 to 9-hydroxy-risperidone, which has a similar pharmacological activity as risperidone. Risperidone plus 9-hydroxy-risperidone form the active antipsychotic fraction. CYP 2D6 is subject to genetic polymorphism. Extensive CYP 2D6 metabolisers convert risperidone rapidly into 9-hydroxy-risperidone, whereas poor CYP 2D6 metabolisers convert it much more slowly. Although extensive metabolisers have lower risperidone and higher 9-hydroxy-risperidone concentrations than poor metabolisers, the pharmacokinetics of risperidone and 9-hydroxy-risperidone combined (i.e., the active antipsychotic fraction), after single and multiple doses, are similar in extensive and poor metabolisers of CYP 2D6.

Another metabolic pathway of risperidone is N-dealkylation. *In vitro* studies in human liver microsomes showed that risperidone at clinically relevant concentration does not substantially inhibit the metabolism of medicines metabolised by cytochrome P450 isozymes, including CYP 1A2, CYP 2A6, CYP 2C8/9/10, CYP 2D6, CYP 2E1, CYP 3A4, and CYP 3A5. One week after administration, 70% of the dose is excreted in the urine and 14% in the faeces. In urine, risperidone plus 9-hydroxy-risperidone represent 35-45% of the dose. The remainder is inactive metabolites. After oral administration to psychotic patients, risperidone is eliminated with a half-life of about 3 hours. The elimination half-life of 9-hydroxy-risperidone and of the active antipsychotic fraction is 24 hours.

Linearity

Risperidone plasma concentrations are dose-proportional within the therapeutic dose-range.

Elderly, hepatic and renal impairment

A single-dose study showed on average a 43% higher active antipsychotic fraction plasma concentrations, a 38% longer half-life and a reduced clearance of the active antipsychotic fraction by 30% in the elderly.Higher active antipsychotic fraction plasma concentrations and a reduced clearance of the active antipsychotic fraction by on average 60% were observed in patients with renal insufficiency. Risperidone plasma concentrations were normal in patients with liver insufficiency, but the mean free fraction of risperidone in plasma was increased by about 35%.

Paediatric patients

The pharmacokinetics of risperidone, 9-hydroxy-risperidone and the active antipsychotic fraction in children are similar to those in adults.

Gender, race and smoking habits

A population pharmacokinetic analysis revealed no apparent effect of gender, race or smoking habits on the pharmacokinetics of risperidone or the active antipsychotic fraction.

5.3 Preclinical safety data

In (sub)chronic toxicity studies, in which dosing was started in sexually immature rats and dogs, dose-dependant effects were present in male and female genital tract and mammary gland. These effects were related to the increased serum prolactin levels, resulting from the dopamine D_2-receptor blocking activity of risperidone. In addition, tissue culture studies suggest that cell growth in human breast tumours may be stimulated by prolactin. Risperidone was not teratogenic in rat and rabbit. In rat reproduction studies with risperidone, adverse effects were seen on mating behaviour of the parents, and on the birth weight and survival of the offspring. In rats, intrauterine exposure to risperidone was associated with cognitive deficits in adulthood. Other dopamine antagonists, when administered to pregnant animals, have caused negative effects on learning and motor development in the offspring. Risperidone was not genotoxic in a battery of tests. In oral carcinogenicity studies of risperidone in rats and mice, increases in pituitary gland adenomas (mouse), endocrine pancreas adenomas (rat), and mammary gland adenomas (both species) were seen. These tumours can be related to prolonged dopamine D_2 antagonism and hyperprolactinaemia. The relevance of these tumour findings in rodents in terms of human risk is unknown. In vitro and in vivo, animal models show that at high doses risperidone may cause QT interval prolongation, which has been associated with a theoretically increased risk of torsade de pointes in patients.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

[To be completed nationally]

6.2 Incompatibilities

[To be completed nationally]

6.3 Shelf life

[To be completed nationally]

6.4 Special precautions for storage

[To be completed nationally]

6.5 Nature and contents of container

[To be completed nationally.]

6.6 Special precautions for disposal and other handling

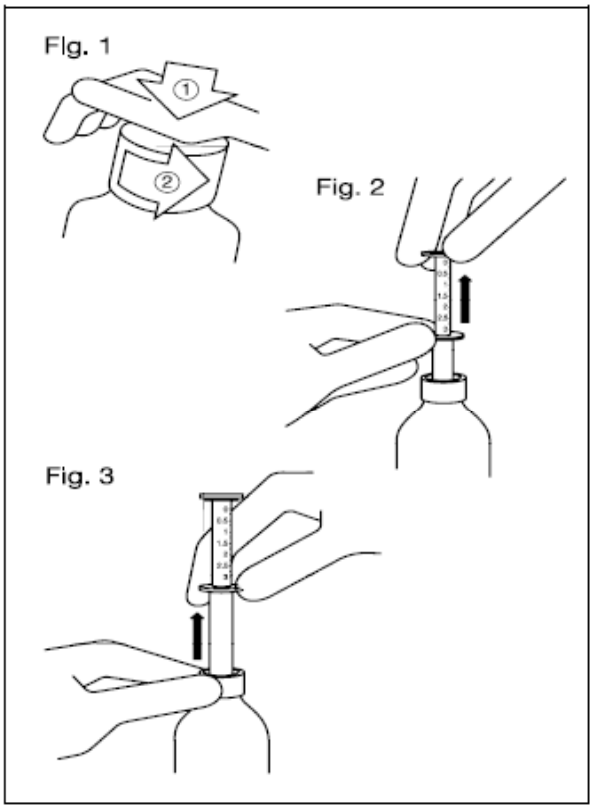
Oro-dispersible Tablets (see section 4.2)

Oral Solution

Fig. 1: The bottle comes with a child-resistant cap, and should be opened as follows:
–Push the plastic screw cap down while turning it counter clockwise.
–Remove the unscrewed cap.

Fig. 2: Insert the pipette into the bottle. While holding the bottom ring, pull the top ring up to the mark that corresponds to the number of millilitres or milligrams you need to give.

Fig.3: Holding the bottom ring, remove the entire pipette from the bottle. Empty the pipette into any non-alcoholic drink, except for tea, by sliding the upper ring down. Close the bottle. Rinse the pipette with some water.



7. MARKETING AUTHORISATION HOLDER

See Annex I - To be completed nationally

{Name and address}

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton for PVC-PE-PVDC/Al blister

1. NAME OF THE MEDICINAL PRODUCT

RISPERDAL and associated names (see Annex I) 0.25 mg film-coated tablets

risperidone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[To be completed nationally]

3. LIST OF EXCIPIENTS

[To be completed nationally]

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet
[To be completed nationally]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

[To be completed nationally]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

{Name and Address}

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton for PVC-PE-PVDC/Al blister

1. NAME OF THE MEDICINAL PRODUCT

RISPERDAL and associated names (see Annex I) 0.5 mg film-coated tablet

risperidone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[To be completed nationally]

3. LIST OF EXCIPIENTS

[To be completed nationally]

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet
[To be completed nationally]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

[To be completed nationally]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

{Name and Address}

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton for PVC-PE-PVDC/Al blister

1. NAME OF THE MEDICINAL PRODUCT

RISPERDAL and associated names (see Annex I) 1 mg film-coated tablets

risperidone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[To be completed nationally]

3. LIST OF EXCIPIENTS

[To be completed nationally]

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet
[To be completed nationally]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

[To be completed nationally]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

{Name and Address}

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton for PVC-PE-PVDC/Al blister

1. NAME OF THE MEDICINAL PRODUCT

RISPERDAL and associated names (see Annex I) 2 mg film-coated tablets

risperidone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[To be completed nationally]

3. LIST OF EXCIPIENTS

[To be completed nationally].

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet
[To be completed nationally]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

[To be completed nationally]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

{Name and Address}

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton for PVC-PE-PVDC/Al blister

1. NAME OF THE MEDICINAL PRODUCT

RISPERDAL and associated names (see Annex I) 3 mg film-coated tablets

risperidone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[To be completed nationally]

3. LIST OF EXCIPIENTS

[To be completed nationally]

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet
[To be completed nationally]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

[To be completed nationally]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

{Name and Address}

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton for PVC-PE-PVDC/Al blister

1. NAME OF THE MEDICINAL PRODUCT

RISPERDAL and associated names (see Annex I) 4 mg film-coated tablets

risperidone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[To be completed nationally]

3. LIST OF EXCIPIENTS

[To be completed nationally]

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet
[To be completed nationally]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

[To be completed nationally]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

{Name and Address}

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton for PVC-PE-PVDC/Al blister

1. NAME OF THE MEDICINAL PRODUCT

RISPERDAL and associated names (see Annex I) 6 mg film-coated tablets

risperidone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[To be completed nationally]

3. LIST OF EXCIPIENTS

[To be completed nationally]

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet
[To be completed nationally]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

[To be completed nationally]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

{Name and Address}

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

PVC-PE-PVDC/Al blister

1. NAME OF THE MEDICINAL PRODUCT

RISPERDAL and associated names (see Annex I) 0.25 mg film-coated tablets
RISPERDAL and associated names (see Annex I) 0.5 mg film-coated tablets
RISPERDAL and associated names (see Annex I) 1 mg film-coated tablets
RISPERDAL and associated names (see Annex I) 2 mg film-coated tablets
RISPERDAL and associated names (see Annex I) 3 mg film-coated tablets
RISPERDAL and associated names (see Annex I) 4 mg film-coated tablets
RISPERDAL and associated names (see Annex I) 6 mg film-coated tablets

risperidone

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

{Name}

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch

5. OTHER

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

PVC-PE-PVDC/Al blister [6 mg calendar pack only]

1. NAME OF THE MEDICINAL PRODUCT

RISPERDAL and associated names (see Annex I) 6 mg film-coated tablets

risperidone

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

{Name}

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch

5. OTHER

[Abbreviation for 7 days of the week.]

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Plastic bottle

1. NAME OF THE MEDICINAL PRODUCT

RISPERDAL and associated names (see Annex I) 0.5 mg film-coated tablets

risperidone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[To be completed nationally]

3. LIST OF EXCIPIENTS

[To be completed nationally]

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet
[To be completed nationally.]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

[To be completed nationally]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally.]

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally.]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally.]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Not applicable

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Plastic bottle

1. NAME OF THE MEDICINAL PRODUCT

RISPERDAL and associated names (see Annex I) 1 mg film-coated tablets

risperidone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[To be completed nationally]

3. LIST OF EXCIPIENTS

[To be completed nationally]

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet
[To be completed nationally.]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

[To be completed nationally]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally.]

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally.]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally.]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Not applicable.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Plastic bottle

1. NAME OF THE MEDICINAL PRODUCT

RISPERDAL and associated names (see Annex I) 2 mg film-coated tablets

risperidone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[To be completed nationally]

3. LIST OF EXCIPIENTS

[To be completed nationally]

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet
[To be completed nationally.]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

[To be completed nationally]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To completed nationally.]

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally.]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally.]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Not applicable

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton for Foil/Foil blister (PVC-Al-Polyamide/4511 heat seal coating/A1-polyester paper)

1. NAME OF THE MEDICINAL PRODUCT

RISPERDAL and associated names (see Annex I) 0.5 mg orodispersible tablets
RISPERDAL and associated names (see Annex I) 1 mg orodispersible tablets
RISPERDAL and associated names (see Annex I) 2 mg orodispersible tablets
RISPERDAL and associated names (see Annex I) 3 mg orodispersible tablets
RISPERDAL and associated names (see Annex I) 4 mg orodispersible tablets

risperidone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[To be completed nationally]

3. LIST OF EXCIPIENTS

[To be completed nationally]

4. PHARMACEUTICAL FORM AND CONTENTS

Orodispersible tablet
[To be completed nationally]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.
Peel open the blister and tip the tablet out
Do not push the tablet through the foil
Melts on the tongue.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

[To be completed nationally]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

{Name and Address}

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton for Film/Foil Blister (PVC-PE-PCTFE/Al blister)

1. NAME OF THE MEDICINAL PRODUCT

RISPERDAL and associated names (see Annex I) 0.5 mg orodispersible tablets
RISPERDAL and associated names (see Annex I) 1 mg orodispersible tablets
RISPERDAL and associated names (see Annex I) 2 mg orodispersible tablets
RISPERDAL and associated names (see Annex I) 3 mg orodispersible tablets
RISPERDAL and associated names (see Annex I) 4 mg orodispersible tablets

risperidone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[To be completed nationally]

3. LIST OF EXCIPIENTS

[To be completed nationally]

4. PHARMACEUTICAL FORM AND CONTENTS

Orodispersible tablet
[To be completed nationally]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.
Peel open the blister and tip the tablet out
Do not push the tablet through the foil
Melts on the tongue.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

[To be completed nationally]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

{Name and Address}

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Foil/Foil blister (PVC-Al-Polyamide/4511 heat seal coating/A1-polyester paper)
Film/Foil Blister (PVC-PE-PCTFE/Al blister)

1. NAME OF THE MEDICINAL PRODUCT

RISPERDAL and associated names (see Annex I) 0.5 mg orodispersible tablets
RISPERDAL and associated names (see Annex I) 1 mg orodispersible tablets
RISPERDAL and associated names (see Annex I) 2 mg orodispersible tablets
RISPERDAL and associated names (see Annex I) 3 mg orodispersible tablets
RISPERDAL and associated names (see Annex I) 4 mg orodispersible tablets

risperidone

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

{Name}

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton for amber glass bottle

1. NAME OF THE MEDICINAL PRODUCT

RISPERDAL and associated names (see Annex I) 1 mg/ml oral solution

risperidone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[To be completed nationally]

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Oral solution

[To be completed nationally]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.
Administration: To facilitate accurate measurement, use the enclosed calibrated pipette or a graduated measure.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP:
Use within 3 months of first opening.

9. SPECIAL STORAGE CONDITIONS

[To be completed nationally]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

{Name and Address}

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

amber glass bottle

1. NAME OF THE MEDICINAL PRODUCT

RISPERDAL and associated names (see Annex I) 1 mg/ml oral solution

risperidone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[To be completed nationally]

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Oral solution

[To be completed nationally.]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.
Administration: To facilitate accurate measurement, use the enclosed calibrated pipette or a graduated measure.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP:
Use within 3 months of first opening. Date opened……..

9. SPECIAL STORAGE CONDITIONS

[To be completed nationally]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

{Name and Address}

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

RISPERDAL and associated names (see Annex I) 0.25, 0.5, 1, 2, 3, 4 and 6 mg film-coated tablets
RISPERDAL Quicklet and associated names (see Annex I): 0.5, 1, 2, 3 and 4 mg orodispersible tablets
RISPERDAL and associated names (see Annex I) 1 mg/ml oral solution
[See Annex I – To be completed nationally)
Risperidone

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT RISPERDAL IS AND WHAT IT IS USED FOR

RISPERDAL belongs to a group of medicines called 'anti-psychotics'.

RISPERDAL is used to treat the following:

- Schizophrenia, where you may see, hear or feel things that are not there, believe things that are not true or feel unusually suspicious, or confused
- Mania, where you may feel very excited, elated, agitated, enthusiastic or hyperactive Mania occurs in an illness called "bipolar disorder"
- Short-term treatment (up to 6 weeks) of long-term aggression in people with Alzheimer's dementia, who harm themselves or others. Alternative (non-drug) treatments should have been used previously
- Short-term treatment (up to 6 weeks) of long-term, aggression in intellectually disabled children (at least 5 years of age) and adolescents with conduct disorder.

2. BEFORE YOU TAKE RISPERDAL

Do not take RISPERDAL if:
- You are allergic (hypersensitive) to risperidone or any of the other ingredients of RISPERDAL (listed in Section 6 below).

If you are not sure if the above applies to you, talk to your doctor or pharmacist before using RISPERDAL.

Take special care with RISPERDAL
Check with your doctor or pharmacist before taking RISPERDAL if:

- You have a heart problem. Examples include an irregular heart rhythm or if you are prone to low blood pressure or if you are using medicines for your blood pressure. RISPERDAL may cause low blood pressure. Your dose may need to be adjusted
- You know of any factors which would favour you having a stroke, such as high blood pressure, cardiovascular disorder or blood vessel problems in the brain
- You have Parkinson's disease or dementia
- You are diabetic
- You have epilepsy
- You are a man and you have ever had a prolonged or painful erection If you experience this while taking RISPERDAL, contact your doctor straight away
- You have problems controlling your body temperature or overheating
- You have kidney problems
- You have liver problems
- You have an abnormally high level of the hormone prolactin in your blood or if you have a tumour, which is possibly dependent on prolactin.

Tell your doctor immediately if you experience
- involuntary rhythmic movements of the tongue, mouth and face. Withdrawal of risperidone may be needed
- fever, severe muscle stiffness, sweating or a lowered level of consciousness (a disorder called "neuroleptic malignant syndrome). Immediate medical treatment may be needed.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using RISPERDAL.

RISPERDAL may cause you to gain weight.

Elderly people with dementia
In elderly patients with dementia, there is an increased risk of stroke . You should not take risperidone if you have dementia caused by stroke.
During treatment with risperidone you should frequently see your doctor.
Medical treatment should be sought straight away if you or your care-giver notice a sudden change in your mental state or sudden weakness or numbness of your face, arms or legs, especially on one side, or slurred speech, even for a short period of time. These may be signs of a stroke.

Children and adolescents
Before treatment is started in conduct disorder, other causes of aggressive behaviour should have been ruled out.
If during treatment with risperidone tiredness occurs, a change in the time of administration might improve attention difficulties.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription and herbal medicines.

It is especially important to talk to your doctor or pharmacist if you are taking any of the following :
- Medicines that work on your brain such as to help you calm down (benzodiazepines) or some medicines for pain (opiates), medicines for allergy (some antihistamines), as risperidone may increase the sedative effect of all of these
- Medicines that may change the electrical activity of your heart, such as medicines for malaria, heart rhythm problems (such as quinidine), allergies (anti-histamines), some antidepressants or other medicines for mental problems
- Medicines that cause a slow heart beat
- Medicines that cause low blood potassium (e.g. certain diuretics)
- Medicines to treat elevated blood pressure. RISPERDAL can lower blood pressure
- Medicines for Parkinson's disease (such as levodopa)

- Water tablets (diuretics) used for heart problems or swelling of parts of your body due to a build up of too much fluid (such as furosemide or chlorothiazide). RISPERDAL taken by itself or with furosemide, may have an increased risk of stroke or death in elderly people with dementia.

The following medicines may reduce the effect of risperidone
- Rifampicin (a medicine for treating some infections)
- Carbamazepine, phenytoin (medicines for epilepsy)
- Phenobarbital

If you start or stop taking such medicines you may need a different dose of risperidone.

The following medicines may increase the effect of risperidone
- Quinidine (used for certain types of heart disease)
- Antidepressants such as paroxetine, fluoxetines, tricyclic antidepressants
- Medicines known as beta blockers (used to treat high blood pressure)
- Phenothiazines (e.g. used to treat psychosis or to calm down)
- Cimetidine, ranitidine (blockers of the acidity of stomach)

If you start or stop taking such medicines you may need a different dose of risperidone.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using RISPERDAL.

Taking RISPERDAL with food and drink
You can take this medicine with or without food. You should avoid drinking alcohol when taking RISPERDAL.

Pregnancy and breast-feeding
- Talk to your doctor before using RISPERDAL if you are pregnant, trying to become pregnant or breast-feeding. Your doctor will decide if you can take it
- Shaking, muscle stiffness and problems feeding, all of which are reversible, have been seen in newborn babies when RISPERDAL was used during the last trimester of pregnancy.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Dizziness, tiredness, and vision problems may occur during treatment with RISPERDAL. Do not drive or use any tools or machines without talking to your doctor first.

Important information about some of the ingredients of RISPERDAL

[To be completed nationally]

3. HOW TO TAKE RISPERDAL

How much to take

For the treatment of schizophrenia

Adults
- The usual starting dose is 2 mg per day, this may be increased to 4 mg per day on the second day
- Your dose may then be adjusted by your doctor depending on how you respond to the treatment
- Most people feel better with daily doses of 4 to 6 mg
- This total daily dose can be divided into either one or two doses a day. Your doctor will tell you which is the best for you.

Elderly people
- Your starting dose will normally be 0.5 mg twice a day
- Your dose may then be gradually increased by your doctor to 1 mg to 2 mg twice a day
- Your doctor will tell you which is the best for you.

Children and adolescents
- Children and adolescents under 18 years old should not be treated with RISPERDAL for schizophrenia.

For the treatment of mania

Adults
- Your starting dose will usually be 2 mg once a day
- Your dose may then be gradually adjusted by your doctor depending on how you respond to the treatment
- Most people feel better with doses of 1 to 6 mg once a day.

Elderly people
- Your starting dose will usually be 0.5 mg twice a day
- Your dose may then be gradually adjusted by your doctor to 1 mg to 2 mg twice a day depending on how much you respond to the treatment.

Children and adolescents
- Children and adolescents under 18 years old should not be treated with RISPERDAL for bipolar mania.

For the treatment of long-standing aggression in people with Alzheimer's dementia

Adults (including elderly people)
- Your starting dose will normally be 0.25 mg twice a day
- Your dose may then be gradually adjusted by your doctor depending on how you respond to the treatment
- Most people feel better with 0.5 mg twice a day. Some patients may need 1 mg twice a day
- Treatment duration in patients with Alzheimer's dementia should be not more than 6 weeks.

For the treatment of conduct disorder in children and adolescents

The dose will depend on your child's weight:

For children who weigh less than 50 kg
- The starting dose will normally be 0.25 mg once a day
- The dose may be increased every other day in steps of 0.25 mg per day.
- The usual maintenance dose is 0.25 mg to 0.75 mg once a day.

For children who weigh 50 kg or more
- The starting dose will normally be 0.5 mg once a day
- The dose may be increased every other day in steps of 0.5 mg per day.
- The usual maintenance dose is 0.5 mg to 1.5 mg once a day.

Treatment duration in patients with conduct disorder should be not more than 6 weeks.

Children under 5 years old should not be treated with RISPERDAL for conduct disorder.

People with kidney or liver problems
Regardless of the disease to be treated, all starting doses and following doses of risperidone should be halved. Dose increases should be slower in these patients.

Risperidone should be used with caution in this patient group.

How to take RISPERDAL

Always take RISPERDAL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how much medicine to take and for how long. This will depend on your condition and varies from person to person. The amount of medicine you should take is explained under the 'How much to take' sub-heading below.

RISPERDAL film-coated tablets

- You should swallow your tablet with a drink of water

RISPERDAL Quicklet orodispersible tablets

Only remove a tablet from the blister when it is time to take your medicine.

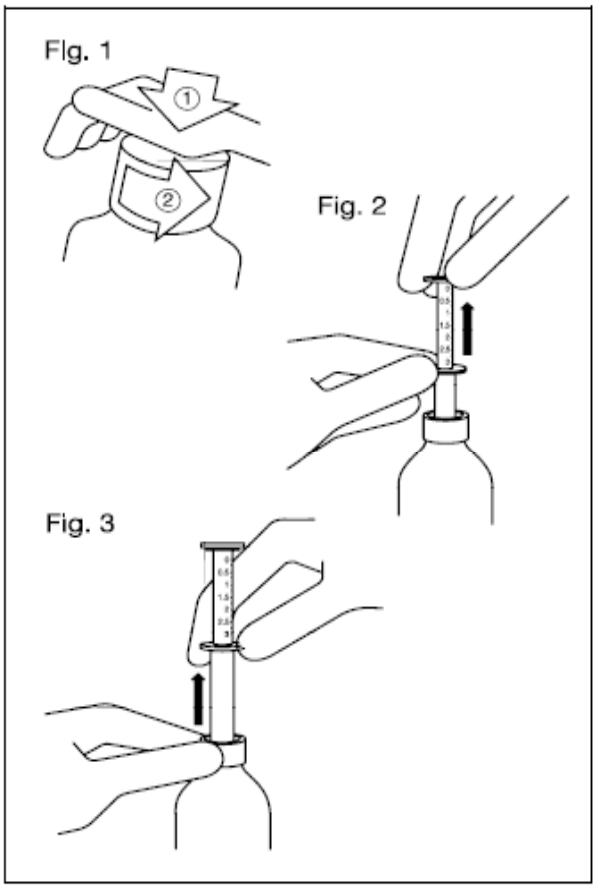
- Peel open a blister to expose the tablet
- Do not push the tablet through the foil because it may break
- Remove the tablet from the blister with dry hands
- Place the tablet on your tongue straight away
- The tablet will begin disintegrating within seconds
- It can then be swallowed with or without water.

RISPERDAL oral solution

The solution comes with a syringe (pipette). This should be used to help you measure the exact amount of medicine you need.

Follow these steps:

1. Remove the child-proof cap. Push the plastic screw cap down while turning it counter clockwise (Figure 1)
2. Insert the syringe into the bottle
3. While holding the bottom ring, pull the top ring up to the mark that corresponds to the number of millilitres or mg you need to take (Figure 2)
4. Holding the bottom ring, remove the entire syringe from the bottle (Figure 3)
5. Empty the syringe into any non-alcoholic drink, except for tea. Slide the upper ring down
6. Close the bottle
7. Rinse the syringe with some water.



If you take more RISPERDAL than you should

- See a doctor right away. Take the medicine pack with you
- In case of overdose you may feel sleepy or tired, or have abnormal body movements, problems standing and walking, feel dizzy due to low blood pressure, or have abnormal heart beats or fits.

If you forget to take RISPERDAL

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual. If you miss two or more doses, contact your doctor
- **Do not take a double dose (two doses at the same time) to make up for a forgotten dose**

If you stop taking RISPERDAL

You should not stop taking this medicine unless told to do so by your doctor. Your symptoms may return. If your doctor decides to stop this medicine, your dose may be decreased gradually over a few days.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, RISPERDAL can cause side effects, although not everybody gets them.

Very common:	affects more than 1 user in 10
Common:	affects 1 to 10 users in 100
Uncommon:	affects 1 to 10 users in 1,000
Rare:	affects 1 to 10 users in 10,000
Very rare:	affects less than 1 user in 10,000
Not known:	frequency cannot be estimated from the available data.

The following side effects may happen:

Very Common (affects more than 1 user in 10):

- Parkinsonism. This is a medical term that includes many symptoms. Each individual symptom may occur less frequently than in 1 in 10 people. Parkinsonism includes: increase in saliva secretion or watery mouth, musculoskeletal stiffness, drooling, jerks when bending the limbs, slow, reduced or impaired body movements, no expression on the face, muscle tightness, stiff neck, muscle stiffness, small, shuffling, hurried steps and lack of normal arm movements when walking, persistent blinking in response to tapping of the forehead (an abnormal reflex)
- Headache, difficulty falling or staying asleep.

Common (affects 1 to 10 users in 100):

- Drowsiness, fatigue, restlessness, inability to sit still, irritability, anxiety, sleepiness, dizziness, poor attention, feeling exhausted, sleep disorder
- Vomiting, diarrhoea, constipation, nausea, increased appetite, abdominal pain or discomfort, sore throat, dry mouth
- Weight increased, increase in body temperature, decreased appetite
- Difficulty breathing, lung infection (pneumonia), flu, infection of the breathing passages, blurred vision, nose congestion, nose bleeding, cough
- Urinary tract infection, bed wetting
- Muscle spasm, involuntary movements of face or arms and legs, joint pain, back pain, swelling of arms and legs, pain in arms and legs
- Rash, skin redness
- Fast beating heart, chest pain
- Blood prolactin hormone level increased.

Uncommon (affects 1 to 10 users in 1000):

- Excessive drinking of water, stool incontinence, thirsty, very hard faeces, hoarseness or voice disorder
- Lung infection caused by inhaling of food into the breathing passages, bladder infection, 'pink eye', sinus infection, viral infection, ear infection, tonsil infection, infection under the skin, eye infection, stomach infection, eye discharge, yeast infection of nails
- Abnormal electrical conduction of the heart, drop in blood pressure after standing, low blood pressure, feeling dizzy after changing body position, abnormal electric activity tracing of the heart (ECG), abnormal heart rhythm, awareness of heart beating, heart rate increased or decreased
- Urinary incontinence, pain when passing urine, frequent passing of urine
- Confused, disturbance in attention, low level of consciousness, excessive sleep, nervousness, elated mood (mania) , lack of energy and interest
- Blood sugar increased, liver enzymes increased, white blood cell count decreased, low haemoglobin or red blood cell count (anaemia), increase in eosinophils (special white blood cells), blood creatinine phosphokinase increased, decrease in platelets (blood cells that help you stop bleeding)
- Muscle weakness, muscle pain, ear pain, neck pain, joint swelling, abnormal posture, joint stiffness, musculoskeletal chest pain, chest discomfort
- Skin lesion, skin disorder, dry skin, intense itching of skin, acne, hair loss, skin inflammation caused by mites, skin discoloration, thickening of skin, flushing, reduced skin sensitivity to pain or touch, inflammation of oily skin
- No menstruation, sexual dysfunction, erectile dysfunction, ejaculation disorder, breast discharge, enlargement of breast in men, decreased sexual drive, irregular menstruation, vaginal discharge
- Fainting, gait disturbance, sluggishness, decreased appetite resulting in malnutrition and low body weight, feeling 'out of sorts', balance disorder, allergy, edema, speech disorder, chills, abnormal coordination
- Painful oversensitivity to light, increased blood flow to the eye, eye swelling, dry eye, increase in tears
- Breathing passage disorder, lung congestion, crackly lung noise, congestion of breathing passages, trouble speaking, difficulty swallowing, cough with sputum, coarse/whistling sound during breathing, flu-like illness, sinus congestion
- Unresponsive to stimuli, loss of consciousness, sudden swelling of lips and eyes along with difficulty breathing, sudden weakness or numbness of the face, arms, or legs, especially on one side, or instances of slurred speech that last for less than 24 hours (these are called mini-strokes or strokes), involuntary movements of face, arms, or legs, ringing in ears, face edema.

Rare (affects 1 to 10 users in 10,000):

- Inability to reach orgasm, menstrual disorder
- Dandruff
- Drug allergy, coldness in arms and legs, lip swelling, lip inflammation
- Glaucoma, reduced visual clarity, eyelid margin crusting, eye rolling
- Lack of emotion
- Change in consciousness with increased body temperature and twitching of muscles, edema all over the body, drug withdrawal syndrome, body temperature decreased
- Fast shallow breathing, trouble breathing during sleep, chronic otitis media
- Obstruction of intestine,
- Reduced blood flow to the brain
- Decrease in white blood cells, inappropriate secretion of a hormone that controls urine volume
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis), movement disorder
- Coma due to uncontrolled diabetes
- Yellowing of the skin and the eyes (jaundice)
- Inflammation of the pancreas.

Very rare (affects less than 1 user in 10,000):

- Life threatening complications of uncontrolled diabetes.

Unknown frequency of occurrence (frequency cannot be estimated from the available data):
- Severe allergic reaction resulting in difficulty in breathing and shock
- No granulocytes (a type of white blood cell to help you against infection)
- Prolonged and painful erection
- Dangerously excessive intake of water.

RISPERDAL CONSTA
The following side effects have been reported with the use of RISPERDAL CONSTA, a long acting injection. Even if you are not being treated with long acting injections of RISPERDAL CONSTA but you experience any of the following, talk to your doctor.

- Infection of the intestine
- Abscess under the skin, tingling pricking or numbness of skin, inflammation of the skin
- Decrease in white blood cell counts that helps to protect you against bacterial infection
- Depression
- Convulsion
- Eye blinking
- Sensation of spinning or swaying
- Slow beating heart, high blood pressure
- Toothache, tongue spasm
- Buttock pain
- Weight decreased.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE RISPERDAL

[To be completed nationally]
Keep out of the reach and sight of children.
Do not use after the expiry date which is stated on the blister, foil, carton, or bottle. The expiry date refers to the last day of that month.

RISPERDAL Quicklet orodispersible tablets

RISPERDAL oral solution

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What RISPERDAL contains

The active substance is risperidone

Each RISPERDAL film-coated tablet contains either 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg or 6 mg of risperidone.

The other ingredients are:
[To be completed nationally]

What RISPERDAL looks like and contents of the pack

[To be completed nationally]

RISPERDAL film-coated Tablets

[To be completed nationally]

RISPERDAL Quicklet orodispersible tablets

[To be completed nationally]

Oral solution

[To be completed nationally]

Marketing Authorisation Holder and Manufacturer

[See Annex I - To be completed nationally]

{Name and address}

This medicinal product is authorised in the Member States of the EEA under the following names:

[To be completed nationally]

Austria:	Risperdal ®/ Rispolin ®/ Risperdal® Quicklet® / Rispolin® Quicklet®
Belgium:	RISPERDAL® / Risperidone J-C ® / RISPERDAL Instasolv ® / Risperidone J-C Instasolv ®
Bulgaria:	РИСПОЛЕПТ®
Cyprus:	RISPERDAL®
Czech Republic:	RISPERDAL®
Denmark:	RISPERDAL®
Estonia:	RISPOLEPT® / RISPOLEPT® QUICKLET®
Finland:	RISPERDAL® / RISPERDAL® INSTASOLV®
France:	RISPERDAL®/ BELIVON® / RISPERDALORO®
Germany:	Belivon / Rehablit / RISPERDAL / RISPERDAL QUICKLET / Risperidon-Janssen
Greece:	RISPERDAL® / RISPERDAL® QUICKLET
Hungary:	RISPERDAL
Iceland:	RISPERDAL®
Ireland:	RISPERDAL® / RISPERDAL® Quicklet®
Italy:	RISPERDAL®/ BELIVON® / ACTASE®
Lithuania:	RISPOLEPT® / RISPOLEPT® Quicklet®
Latvia:	RISPOLEPT® / RISPERDAL® Quicklet®
Liechtenstein:	RISPERDAL® / RISPERDAL® QUICKLET®
Luxembourg:	RISPERDAL® / Risperidone J-C ® RISPERDAL Instasolv ® / Risperidone J-C Instasolv ®
Malta:	RISPERDAL®
Netherlands:	RISPERDAL®/ BELIVON® / RISPERDAL Quicklet ®
Norway:	RISPERDAL® / RISPERDAL®smeltetabletter
Poland:	RISPOLEPT® / RISPOLEPT® QUICKLET
Portugal:	RISPERDAL® / RISPERDAL® QUICKLET®
Romania:	RISPOLEPT® / RISPOLEPT QUICKLET
Slovakia:	RISPERDAL® / RISPERDAL® QUICKLET®
Slovenia:	RISPERDAL® / RISPERDAL QUICKLET®

Spain:	RISPERDAL® / RISPERDAL® FLAS
Sweden:	RISPERDAL®/ BELIVON®
United Kingdom:	RISPERDAL®/ RISPERDAL® Quicklet®

This leaflet was last approved in {MM/YYYY}.

[To be completed nationally]

ANNEX IV

CONDITIONS OF THE MARKETING AUTHORISATIONS

The National Competent Authorities, coordinated by the Reference Member State, shall ensure that the following conditions are fulfilled by the Marketing Authorisation Holders:

The Marketing Authorisation Holder commits to generate a collection of long-term data for the evaluation of long-term safety of risperidone in children and adolescents with conduct disorder in terms of potential effects on growth (height and weight), mental development, and sexual maturation (by Tanner stage). The study should also assess prolactin values and possible prolactin-related AEs. Regarding cognitive assessment, the MAH should make a proposal as to how it would be possible to assess effects on cognitive development.