

## **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 EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Austria	Janssen-Cilag Pharma GmbH Vorgartenstraße 206B AT-1020 Vienna Austria	Haldol	2 mg/ml	Oral solution	Oral use	2 mg/ml
Austria	Janssen-Cilag Pharma GmbH Vorgartenstraße 206B AT-1020 Vienna Austria	Haldol	150 mg/30 ml	Solution for injection	Intramuscular use	5 mg/ml
Austria	Janssen-Cilag Pharma GmbH Vorgartenstraße 206B AT-1020 Vienna Austria	Haldol	1 mg	Tablet	Oral use	N/A
Austria	Janssen-Cilag Pharma GmbH Vorgartenstraße 206B AT-1020 Vienna Austria	Haldol	10 mg	Tablet	Oral use	N/A
Belgium	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	30 mg/15 ml	Oral solution	Oral use	2 mg/ml
Belgium	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	60 mg/30 ml	Oral solution	Oral use	2 mg/ml
Belgium	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	200 mg/100 ml	Oral solution	Oral use	2 mg/ml
Belgium	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	300 mg/30 ml	Oral solution	Oral use	10 mg/ml

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Belgium	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	1000 mg/100 ml	Oral solution	Oral use	10 mg/ml
Belgium	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	5 mg/ml	Solution for injection	Intramuscular use; Intravenous use	5 mg/ml
Belgium	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	2 mg	Tablet	Oral use	N/A
Belgium	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	5 mg	Tablet	Oral use	N/A
Belgium	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	20 mg	Tablet	Oral use	N/A
Cyprus	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, Belgium	Haldol	30 mg/15 ml	Oral solution	Oral use	2 mg/ml
Cyprus	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, Belgium	Haldol	5 mg/ml	Solution for injection	Intramuscular use	5 mg/ml
Cyprus	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, Belgium	Haldol	5 mg	Tablet	Oral use	N/A

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Denmark	JANSSEN-CILAG A/S Bregnerødvej 133 3460 Birkerød Denmark	Serenase	2 mg/ml	Oral solution	Oral use	2 mg/ml
Denmark	JANSSEN-CILAG A/S Bregnerødvej 133 3460 Birkerød Denmark	Serenase	5 mg/ml	Solution for injection	Intramuscular use; Intravenous use	5 mg/ml
Denmark	JANSSEN-CILAG A/S Bregnerødvej 133 3460 Birkerød Denmark	Serenase	2 mg	Tablet	Oral use	N/A
Denmark	JANSSEN-CILAG A/S Bregnerødvej 133 3460 Birkerød Denmark	Serenase	5 mg	Tablet	Oral use	N/A
Denmark	JANSSEN-CILAG A/S Bregnerødvej 133 3460 Birkerød Denmark	Serenase	20 mg	Tablet	Oral use	N/A
Finland	Janssen-Cilag Oy Vaisalantie 2 02130 Espoo Finland	Serenase	2 mg/ml	Oral solution	Oral use	2 mg/ml
Finland	Janssen-Cilag Oy Vaisalantie 2 02130 Espoo	Serenase	5 mg/ml	Solution for injection	Intramuscular use	5 mg/ml
Finland	Janssen-Cilag Oy Vaisalantie 2 02130 Espoo Finland	Serenase	1 mg	Tablet	Oral use	N/A

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Finland	Janssen-Cilag Oy Vaisalantie 2 02130 Espoo Finland	Serenase	4 mg	Tablet	Oral use	N/A
Finland	Janssen-Cilag Oy Vaisalantie 2 02130 Espoo Finland	Serenase	10 mg	Tablet	Oral use	N/A
France	Janssen-Cilag 1, rue Camille Desmoulins, TSA 91003 F-92787 Issy Les Moulineaux, Cedex 9 France	Haldol	2 mg/ml in bottles of 15 ml, 30 ml, 100 ml and 195 ml	Oral solution	Oral use	2 mg/ml
France	Janssen-Cilag 1, rue Camille Desmoulins, TSA 91003 F-92787 Issy Les Moulineaux, Cedex 9 France	Haldol	5 mg/ml	Solution for injection	Intramuscular use	5 mg/ml
France	Janssen-Cilag 1, rue Camille Desmoulins, TSA 91003 F-92787 Issy Les Moulineaux, Cedex 9 France	Haldol	1 mg	Tablet	Oral use	N/A
France	Janssen-Cilag 1, rue Camille Desmoulins, TSA 91003 F-92787 Issy Les Moulineaux, Cedex 9 France	Haldol	5 mg	Tablet	Oral use	N/A

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Germany	Janssen-Cilag GmbH Johnson & Johnson Platz 1 41470 Neuss Germany	Haldol-Janssen	2 mg/ ml in bottles of 30 ml and 100 ml)	Oral solution	Oral use	2 mg/ml
Germany	Janssen-Cilag GmbH Johnson & Johnson Platz 1 41470 Neuss Germany	Haldol-Janssen	5 mg/ml	Solution for injection	Intramuscular use	5 mg/ml
Germany	Janssen-Cilag GmbH Johnson & Johnson Platz 1 41470 Neuss Germany	Haldol-Janssen	1 mg	Tablet	Oral use	N/A
Germany	Janssen-Cilag GmbH Johnson & Johnson Platz 1 41470 Neuss Germany	Haldol-Janssen	2 mg	Tablet	Oral use	N/A
Germany	Janssen-Cilag GmbH Johnson & Johnson Platz 1 41470 Neuss Germany	Haldol-Janssen	5 mg	Tablet	Oral use	N/A
Germany	Janssen-Cilag GmbH Johnson & Johnson Platz 1 41470 Neuss Germany	Haldol-Janssen	10 mg	Tablet	Oral use	N/A
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave, Pefki Athens GR-151 21 Greece	Aloperidin	30 mg/15 ml	Oral Drops, Solution	Oral use	2 mg/ml

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave, Pefki Athens GR-151 21 Greece	Aloperidin	150 mg/15 ml 300mg/30ml	Oral Drops, Solution	Oral use	10 mg/ml
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave, Pefki Athens GR-151 21 Greece	Aloperidin	5 mg/ml (BTx5AMP x1ML, BTx50AMP x1ML )	Solution for injection	Intramuscular use	5 mg/ml
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave, Pefki, Athens GR-151 21 Greece	Aloperidin	1 mg	Tablet	Oral use	N/A
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave, Pefki, Athens GR-151 21 Greece	Aloperidin	2 mg	Tablet	Oral use	N/A
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave, Pefki, Athens GR-151 21 Greece	Aloperidin	5 mg	Tablet	Oral use	N/A
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave, Pefki, Athens GR-151 21 Greece	Aloperidin	10 mg	Tablet	Oral use	N/A
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave, Pefki, Athens GR-151 21 Greece	Aloperidin	20 mg	Tablet	Oral use	N/A

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Iceland	Janssen-Cilag AB Box 4042 16904 Solna Sweden	Haldol	5 mg/ml	Solution for injection	Intramuscular use	5 mg/ml
Iceland	Janssen-Cilag AB Box 4042 16904 Solna Sweden	Haldol	1 mg	Tablet	Oral use	N/A
Iceland	Janssen-Cilag AB Box 4042 16904 Solna Sweden	Haldol	4 mg	Tablet	Oral use	N/A
Italy	Janssen-Cilag SpA Via M.Buonarroti, 23 I-20093 Cologno Monzese MI, Italy	Haldol	60 mg/30 ml	Oral drops,	Oral use	2 mg/ml
Italy	Janssen-Cilag SpA Via M.Buonarroti, 23 I-20093 Cologno Monzese MI, Italy	Haldol	300 mg/30 ml	Oral drops, solution	Oral use	10 mg/ml
Italy	Janssen-Cilag SpA Via M.Buonarroti, 23 I-20093 Cologno Monzese MI, Italy	Haldol	5 mg/ml	Solution for injection	Intramuscular use	5 mg/ml
Italy	Janssen-Cilag SpA Via M.Buonarroti, 23 I-20093 Cologno Monzese MI, Italy	Haldol	1 mg	Tablet	Oral use	N/A

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Italy	Janssen-Cilag SpA Via M.Buonarroti, 23 I-20093 Cologno Monzese MI, Italy	Haldol	5 mg	Tablet	Oral use	N/A
Luxembourg	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	30 mg/15 ml	Oral solution	Oral use	2 mg/ml
Luxembourg	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	60 mg/30 ml	Oral solution	Oral use	2 mg/ml
Luxembourg	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	200 mg/100 ml	Oral solution	Oral use	2 mg/ml
Luxembourg	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	300 mg/30 ml	Oral solution	Oral use	10 mg/ml
Luxembourg	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	1000 mg/100 ml	Oral solution	Oral use	10 mg/ml
Luxembourg	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	5 mg/ml	Solution for injection	Intramuscular use; Intravenous use	5 mg/ml
Luxembourg	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	2 mg	Tablet	Oral use	N/A

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Luxembourg	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	5 mg	Tablet	Oral use	N/A
Luxembourg	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	20 mg	Tablet	Oral use	N/A
Malta	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse Belgium	Haldol	5 mg	Tablet	Oral use	N/A
The Netherlands	Janssen-Cilag BV Dr. Paul Janssenweg 150 5026 RH Tilburg The Netherlands	Haldol druppels 2 mg/ml	60 mg/30 ml	Oral solution	Oral use	2 mg/ml
The Netherlands	Janssen-Cilag BV Dr. Paul Janssenweg 150 5026 RH Tilburg The Netherlands	Haldol oplossing voor injectie 5 mg/ml	5 mg/ml	Solution for injection	Intramuscular use; Intravenous use	5 mg/ml
The Netherlands	Janssen-Cilag BV Dr. Paul Janssenweg 150 5026 RH Tilburg The Netherlands	Haldol tabletten 10 mg	10 mg	Tablet	Oral use	N/A
Norway	JANSSEN-CILAG AS Drammensveien 288 0283 Oslo Norway	Haldol	5 mg/ml	Solution for injection	Intramuscular use	5 mg/ml
Norway	JANSSEN-CILAG AS Drammensveien 288 0283 Oslo Norway	Haldol	1 mg	Tablet	Oral use	N/A

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Norway	JANSSEN-CILAG AS Drammensveien 288 0283 Oslo Norway	Haldol	4 mg	Tablet	Oral use	N/A
Portugal	Janssen Farmacéutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A, Queluz de Baixo 2734 503 Barcarena Portugal	Haldol	2 mg/ml	Oral solution	Oral use	2 mg/ml
Portugal	Janssen Farmacéutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A, Queluz de Baixo 2734 503 Barcarena Portugal	Haldol	1 mg	Tablet	Oral use	N/A
Portugal	Janssen Farmacéutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A, Queluz de Baixo 2734 503 Barcarena Portugal	Haldol	2 mg	Tablet	Oral use	N/A
Portugal	Janssen Farmacéutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A, Queluz de Baixo 2734 503 Barcarena Portugal	Haldol	5 mg	Tablet	Oral use	N/A

Member State EU/EEA	Marketing authorisation holder	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	Haldol	10 mg	Tablet	Oral use	N/A
Romania	Janssen Pharmaceutica N.V. Turnhoutseweg 30, B- 2340 Beerse Belgium	Haldol	5 mg	Tablet	Oral use	N/A
Sweden	Janssen-Cilag AB Box 4042 16904 Solna Sweden	Haldol	200 mg/100 ml	Oral solution	Oral use	2 mg/ml
Sweden	Janssen-Cilag AB Box 4042 16904 Solna Sweden	Haldol	5 mg/ml	Solution for injection	Intramuscular use	5 mg/ml
Sweden	Janssen-Cilag AB Box 4042 16904 Solna Sweden	Haldol	1 mg	Tablet	Oral use	NA
Sweden	Janssen-Cilag AB Box 4042 16904 Solna Sweden	Haldol	4 mg	Tablet	Oral use	NA
United Kingdom	Janssen-Cilag Limited 50-100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG United Kingdom	Haldol	2 mg/ml	Oral solution	Oral use	N/A

<b>Member State EU/EEA</b>	<b>Marketing authorisation holder</b>	<b>Name</b>	<b>Strength</b>	<b>Pharmaceutical form</b>	<b>Route of administration</b>	<b>Content (concentration)</b>
United Kingdom	Janssen-Cilag Limited 50-100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG United Kingdom	Haldol	5 mg/ml	Solution for injection	Intramuscular use	5 mg/ml
United Kingdom	Janssen-Cilag Limited 50-100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG United Kingdom	Haldol	10 mg/2 ml	Solution for injection	Intramuscular use	5 mg/ml