13 January 2023
EMA/21406/2023
Human Medicines Division

# List of nationally authorised medicinal products

Active substance(s): risperidone

Procedure No. PSUSA/00002649/202205

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| Eperon 8 mg επικαλυμμένα με λεπτό υμένιο δισκία | DK/H/0980/007 | 20183 | MEDOCHEMIE LTD. | CY |
| Risperanne, filmovertrukne tabletter | DE/H/0794/001 | 39628 | SANDOZ A/S | DK |
| Risperdal | DE/H/2184/002 | 30230 | JANSSEN-CILAG A/S | DK |
| Risperdal | DE/H/2184/004 | 14977 | JANSSEN-CILAG A/S | DK |
| Risperdal | DE/H/2184/003 | 14976 | JANSSEN-CILAG A/S | DK |
| Risperdal | DE/H/2184/006 | 14979 | JANSSEN-CILAG A/S | DK |
| Risperdal | DE/H/2184/008 | 17570 | JANSSEN-CILAG A/S | DK |
| Risperdal | DE/H/2184/005 | 14978 | JANSSEN-CILAG A/S | DK |
| RISPERDAL 0,5 mg comprimés pelliculés | DE/H/2184/002 | BE449600 | JANSSEN-CILAG NV | BE |
| RISPERDAL 0,5 mg comprimés pelliculés | DE/H/2184/002 | BE219983 | JANSSEN-CILAG NV | BE |
| RISPERDAL 0,5 mg comprimés pelliculés | DE/H/2184/002 | 2001040022 | JANSSEN-CILAG NV | LU |
| RISPERDAL 0,5 mg comprimidos revestidos por película | DE/H/2184/002 | 3219888 | JANSSEN FARMACÊUTICA PORTUGAL, LDA | PT |
| Risperdal 0,5 mg filmdragerade tabletter | DE/H/2184/002 | 14318 | JANSSEN-CILAG AB | SE |
| RISPERDAL 0,5 mg filmomhulde tabletten | DE/H/2184/002 | BE449600 | JANSSEN-CILAG NV | BE |
| RISPERDAL 0,5 mg filmomhulde tabletten | DE/H/2184/002 | BE219983 | JANSSEN-CILAG NV | BE |
| Risperdal 0,5 mg Filmtabletten | DE/H/2184/002 | BE219983 | JANSSEN-CILAG NV | BE |
| Risperdal 0,5 mg Filmtabletten | DE/H/2184/002 | BE449600 | JANSSEN-CILAG NV | BE |
| Risperdal 0,5 mg Filmtabletten | DE/H/2184/002 | 2001040022 | JANSSEN-CILAG NV | LU |
| Risperdal 0,5 mg filmuhúðaðar töflur | DE/H/2184/002 | 980135 | JANSSEN-CILAG AB | IS |
| Risperdal 0,5 mg | DE/H/2184/002 | 98-4328 | JANSSEN-CILAG A/S | NO |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| tabletter, filmdrasjerte | | | | |
| RISPERDAL 0,5 mg tabletti, kalvopäällysteinen | DE/H/2184/002 | 13364 | JANSSEN-CILAG OY | FI |
| RISPERDAL 0,5 mg, filmomhulde tabletten | DE/H/2184/002 | RVG 22714 | JANSSEN-CILAG BV | NL |
| RISPERDAL 0,5 mg, Filmtabletten | DE/H/2184/002 | 43776.01.00 | JANSSEN-CILAG GMBH | DE |
| RISPERDAL 0.5 mg film-coated tablets | DE/H/2184/002 | PA22612/010/009 | JANSSEN SCIENCES IRELAND UC | IE |
| RISPERDAL 0.5 mg film-coated tablets | DE/H/2184/002 | PL 00242/0347 | JANSSEN-CILAG LIMITED | XI |
| Risperdal 1 mg compresse rivestite con film | DE/H/2184/003 | AIC 028752057 | JANSSEN-CILAG SPA | IT |
| Risperdal 1 mg compresse rivestite con film | DE/H/2184/003 | AIC 028752018 | JANSSEN-CILAG SPA | IT |
| RISPERDAL 1 mg comprimés pelliculés | DE/H/2184/003 | BE449617 | JANSSEN-CILAG NV | BE |
| RISPERDAL 1 mg comprimés pelliculés | DE/H/2184/003 | BE165681 | JANSSEN-CILAG NV | BE |
| RISPERDAL 1 mg comprimés pelliculés | DE/H/2184/003 | 2004058265 | JANSSEN-CILAG NV | LU |
| RISPERDAL 1 mg comprimidos recubiertos con película | DE/H/2184/003 | 60.336 | JANSSEN-CILAG S.A. | ES |
| RISPERDAL 1 mg comprimidos revestidos por película | DE/H/2184/003 | 2305886 | JANSSEN FARMACÊUTICA PORTUGAL, LDA | PT |
| RISPERDAL 1 mg film-coated tablets | DE/H/2184/003 | PA22612/010/004 | JANSSEN SCIENCES IRELAND UC | IE |
| RISPERDAL 1 mg film-coated tablets | DE/H/2184/003 | MA018/00201 | JANSSEN-CILAG INTERNATIONAL NV | MT |
| RISPERDAL 1 mg film-coated tablets | DE/H/2184/003 | PL 00242/0186 | JANSSEN-CILAG LIMITED | XI |
| Risperdal 1 mg filmdragerade tabletter | DE/H/2184/003 | 11992 | JANSSEN-CILAG AB | SE |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| RISPERDAL 1 mg filmomhulde tabletten | DE/H/2184/003 | BE449617 | JANSSEN-CILAG NV | BE |
| RISPERDAL 1 mg filmomhulde tabletten | DE/H/2184/003 | BE165681 | JANSSEN-CILAG NV | BE |
| Risperdal 1 mg filmsko obložene tablete | DE/H/2184/003 | H/96/01358/008 | JOHNSON & JOHNSON D.O.O. | SI |
| RISPERDAL 1 mg Filmtabletten | DE/H/2184/003 | 1-20297 | JANSSEN-CILAG PHARMA GMBH | AT |
| Risperdal 1 mg Filmtabletten | DE/H/2184/003 | BE449617 | JANSSEN-CILAG NV | BE |
| Risperdal 1 mg Filmtabletten | DE/H/2184/003 | BE165681 | JANSSEN-CILAG NV | BE |
| Risperdal 1 mg Filmtabletten | DE/H/2184/003 | 2004058265 | JANSSEN-CILAG NV | LU |
| Risperdal 1 mg filmuhúðaðar töflur | DE/H/2184/003 | 920123 | JANSSEN-CILAG AB | IS |
| RISPERDAL 1 mg potahované tablety | DE/H/2184/003 | 68/185/95-A/C | JANSSEN-CILAG S.R.O | CZ |
| Risperdal 1 mg tabletter, filmdrasjerte | DE/H/2184/003 | 8037 | JANSSEN-CILAG A/S | NO |
| RISPERDAL 1 mg tabletti, kalvopäällysteinen | DE/H/2184/003 | 11478 | JANSSEN-CILAG OY | FI |
| RISPERDAL 1 mg επικαλυμμένα με λεπτό υμένιο δισκία | DE/H/2184/003 | 14396 | JANSSEN-CILAG INTERNATIONAL NV | CY |
| RISPERDAL 1 mg επικαλυμμένα με λεπτό υμένιο δισκία | DE/H/2184/003 | 111761/13-12-2017 | JANSSEN-CILAG PHARMACEUTICAL S.A.C.I. | GR |
| RISPERDAL 1 mg, comprimé pelliculé | DE/H/2184/003 | 34009 343 263 9 4 | JANSSEN-CILAG | FR |
| RISPERDAL 1 mg, comprimé pelliculé | DE/H/2184/003 | 34009 338 947 0 2 | JANSSEN-CILAG | FR |
| RISPERDAL 1 mg, comprimé pelliculé | DE/H/2184/003 | 34009 338 948 7 0 | JANSSEN-CILAG | FR |
| RISPERDAL 1 mg, filmomhulde tabletten | DE/H/2184/003 | RVG 16096 | JANSSEN-CILAG BV | NL |
| RISPERDAL 1 mg, | DE/H/2184/003 | 28758.00.00 | JANSSEN-CILAG GMBH | DE |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| Filmtabletten | | | | |
| Risperdal 1 mg/ml belsőleges oldat | DE/H/2184/008 | OGYI-T-8812/07 | JANSSEN-CILAG KFT. | HU |
| RISPERDAL 1 mg/ml drank | DE/H/2184/008 | BE183897 | JANSSEN-CILAG NV | BE |
| RISPERDAL 1 mg/ml drank | DE/H/2184/008 | RVG 19127 | JANSSEN-CILAG BV | NL |
| RISPERDAL 1 mg/ml Lösung zum Einnehmen | DE/H/2184/008 | 1-21466 | JANSSEN-CILAG PHARMA GMBH | AT |
| Risperdal 1 mg/ml Lösung zum Einnehmen | DE/H/2184/008 | BE183897 | JANSSEN-CILAG NV | BE |
| Risperdal 1 mg/ml Lösung zum Einnehmen | DE/H/2184/008 | 2008089904 | JANSSEN-CILAG NV | LU |
| Risperdal 1 mg/ml mikstur, oppløsning | DE/H/2184/008 | 95-0684 | JANSSEN-CILAG A/S | NO |
| Risperdal 1 mg/ml mixtúra, lausn | DE/H/2184/008 | 950155 | JANSSEN-CILAG AB | IS |
| RISPERDAL 1 mg/ml oral lösning | DE/H/2184/008 | 12113 | JANSSEN-CILAG OY | FI |
| Risperdal 1 mg/ml oral lösning | DE/H/2184/008 | 12677 | JANSSEN-CILAG AB | SE |
| RISPERDAL 1 mg/ml oral solution | DE/H/2184/008 | PA22612/010/001 | JANSSEN SCIENCES IRELAND UC | IE |
| Risperdal 1 mg/ml peroralna raztopina | DE/H/2184/008 | H/96/01358/004 | JOHNSON & JOHNSON D.O.O. | SI |
| RISPERDAL 1 mg/ml perorální roztok | DE/H/2184/008 | 68/298/99-C | JANSSEN-CILAG S.R.O | CZ |
| RISPERDAL 1 mg/ml solução oral | DE/H/2184/008 | 2715381 | JANSSEN FARMACÊUTICA PORTUGAL, LDA | PT |
| RISPERDAL 1 mg/ml solución oral | DE/H/2184/008 | 62.096 | JANSSEN-CILAG S.A. | ES |
| RISPERDAL 1 mg/ml solution buvable | DE/H/2184/008 | 2008089904 | JANSSEN-CILAG NV | LU |
| Risperdal 1 mg/ml soluzione orale | DE/H/2184/008 | AIC 028752145 | JANSSEN-CILAG SPA | IT |
| Risperdal 1 mg/ml soluzione orale | DE/H/2184/008 | AIC 028752095 | JANSSEN-CILAG SPA | IT |
| RISPERDAL 1 mg/ml | DE/H/2184/008 | 17844 | JANSSEN-CILAG | CY |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| πόσιμο διάλυμα | | | INTERNATIONAL NV | |
| RISPERDAL 1 mg/ml πόσιμο διάλυμα | DE/H/2184/008 | 111765/13-12-2017 | JANSSEN-CILAG PHARMACEUTICAL S.A.C.I. | GR |
| RISPERDAL 1 mg/ml, solution buvable | DE/H/2184/008 | 34009 343 982 5 4 | JANSSEN-CILAG | FR |
| RISPERDAL 1 mg/ml, solution buvable | DE/H/2184/008 | 34009 343 980 2 5 | JANSSEN-CILAG | FR |
| RISPERDAL 1 mg/ml, solution buvable | DE/H/2184/008 | 34009 343 984 8 3 | JANSSEN-CILAG | FR |
| RISPERDAL 1 mg/ml, solution buvable | DE/H/2184/008 | 34009 343 983 1 5 | JANSSEN-CILAG | FR |
| RISPERDAL 1 mg/ml, solution buvable | DE/H/2184/008 | 34009 343 981 9 3 | JANSSEN-CILAG | FR |
| RISPERDAL 1mg /ml solução oral | DE/H/2184/008 | 2527984 | JANSSEN FARMACÊUTICA PORTUGAL, LDA | PT |
| RISPERDAL 1mg comprimidos revestidos por película | DE/H/2184/003 | 2305985 | JANSSEN FARMACÊUTICA PORTUGAL, LDA | PT |
| RISPERDAL 1mg comprimidos revestidos por película | DE/H/2184/003 | 2305787 | JANSSEN FARMACÊUTICA PORTUGAL, LDA | PT |
| RISPERDAL 1mg/ml oral solution | DE/H/2184/008 | MA018/00204 | JANSSEN-CILAG INTERNATIONAL NV | MT |
| RISPERDAL 1mg/ml oral solution | DE/H/2184/008 | PL 00242/0199 | JANSSEN-CILAG LIMITED | XI |
| RISPERDAL 1mg/ml solution buvable | DE/H/2184/008 | BE183897 | JANSSEN-CILAG NV | BE |
| Risperdal 2 mg compresse rivestite con film | DE/H/2184/004 | AIC 028752020 | JANSSEN-CILAG SPA | IT |
| Risperdal 2 mg compresse rivestite con film | DE/H/2184/004 | AIC 028752069 | JANSSEN-CILAG SPA | IT |
| RISPERDAL 2 mg comprimés pelliculés | DE/H/2184/004 | BE449626 | JANSSEN-CILAG NV | BE |
| RISPERDAL 2 mg comprimés pelliculés | DE/H/2184/004 | BE165697 | JANSSEN-CILAG NV | BE |
| RISPERDAL 2 mg | DE/H/2184/004 | 2004058266 | JANSSEN-CILAG NV | LU |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| comprimés pelliculés | | | | |
| RISPERDAL 2 mg comprimidos revestidos por película | DE/H/2184/004 | 2306082 | JANSSEN FARMACÊUTICA PORTUGAL, LDA | PT |
| RISPERDAL 2 mg comprimidos revestidos por película | DE/H/2184/004 | 2306181 | JANSSEN FARMACÊUTICA PORTUGAL, LDA | PT |
| RISPERDAL 2 mg film-coated tablets | DE/H/2184/004 | PA22612/010/005 | JANSSEN SCIENCES IRELAND UC | IE |
| RISPERDAL 2 mg film-coated tablets | DE/H/2184/004 | MA018/00203 | JANSSEN-CILAG INTERNATIONAL NV | MT |
| RISPERDAL 2 mg film-coated tablets | DE/H/2184/004 | MA018/00203 | JANSSEN-CILAG INTERNATIONAL NV | MT |
| RISPERDAL 2 mg film-coated tablets | DE/H/2184/004 | PL 00242/0187 | JANSSEN-CILAG LIMITED | XI |
| Risperdal 2 mg filmdragerade tabletter | DE/H/2184/004 | 11993 | JANSSEN-CILAG AB | SE |
| RISPERDAL 2 mg filmomhulde tabletten | DE/H/2184/004 | BE449626 | JANSSEN-CILAG NV | BE |
| RISPERDAL 2 mg filmomhulde tabletten | DE/H/2184/004 | BE165697 | JANSSEN-CILAG NV | BE |
| Risperdal 2 mg filmsko obložene tablete | DE/H/2184/004 | H/96/01358/014 | JOHNSON & JOHNSON D.O.O. | SI |
| RISPERDAL 2 mg Filmtabletten | DE/H/2184/004 | 1-20301 | JANSSEN-CILAG PHARMA GMBH | AT |
| Risperdal 2 mg Filmtabletten | DE/H/2184/004 | BE165697 | JANSSEN-CILAG NV | BE |
| Risperdal 2 mg Filmtabletten | DE/H/2184/004 | BE449626 | JANSSEN-CILAG NV | BE |
| Risperdal 2 mg Filmtabletten | DE/H/2184/004 | 2004058266 | JANSSEN-CILAG NV | LU |
| Risperdal 2 mg filmuhúðaðar töflur | DE/H/2184/004 | 920124 | JANSSEN-CILAG AB | IS |
| RISPERDAL 2 mg potahované tablety | DE/H/2184/004 | 68/185/95-B/C | JANSSEN-CILAG S.R.O | CZ |
| Risperdal 2 mg tabletter, filmdrasjerte | DE/H/2184/004 | 8038 | JANSSEN-CILAG A/S | NO |
| RISPERDAL 2 mg | DE/H/2184/004 | 11479 | JANSSEN-CILAG OY | FI |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| tabletti, kalvopäällysteinen | | | | |
| RISPERDAL 2 mg επικαλυμμένα με λεπτό υμένιο δισκία | DE/H/2184/004 | 14397 | JANSSEN-CILAG INTERNATIONAL NV | CY |
| RISPERDAL 2 mg επικαλυμμένα με λεπτό υμένιο δισκία | DE/H/2184/004 | 111762/13-12-2017 | JANSSEN-CILAG PHARMACEUTICAL S.A.C.I. | GR |
| RISPERDAL 2 mg, comprimé pelliculé | DE/H/2184/004 | 34009 338 949 3 1 | JANSSEN-CILAG | FR |
| RISPERDAL 2 mg, comprimé pelliculé | DE/H/2184/004 | 34009 343 264 5 5 | JANSSEN-CILAG | FR |
| RISPERDAL 2 mg, comprimé pelliculé | DE/H/2184/004 | 34009 338 950 1 3 | JANSSEN-CILAG | FR |
| RISPERDAL 2 mg, filmomhulde tabletten | DE/H/2184/004 | RVG 16097 | JANSSEN-CILAG BV | NL |
| RISPERDAL 2 mg, Filmtabletten | DE/H/2184/004 | 28758.01.00 | JANSSEN-CILAG GMBH | DE |
| Risperdal 3 mg compresse rivestite con film | DE/H/2184/005 | AIC 028752071 | JANSSEN-CILAG SPA | IT |
| Risperdal 3 mg compresse rivestite con film | DE/H/2184/005 | AIC 028752032 | JANSSEN-CILAG SPA | IT |
| RISPERDAL 3 mg comprimés pelliculés | DE/H/2184/005 | BE165706 | JANSSEN-CILAG NV | BE |
| RISPERDAL 3 mg comprimés pelliculés | DE/H/2184/005 | 2004058267 | JANSSEN-CILAG NV | LU |
| RISPERDAL 3 mg comprimidos recubiertos con película | DE/H/2184/005 | 60.335 | JANSSEN-CILAG S.A. | ES |
| RISPERDAL 3 mg comprimidos revestidos por película | DE/H/2184/005 | 2306389 | JANSSEN FARMACÊUTICA PORTUGAL, LDA | PT |
| RISPERDAL 3 mg comprimidos revestidos por película | DE/H/2184/005 | 2306280 | JANSSEN FARMACÊUTICA PORTUGAL, LDA | PT |
| RISPERDAL 3 mg film- | DE/H/2184/005 | PA22612/010/006 | JANSSEN SCIENCES | IE |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| coated tablets | | | IRELAND UC | |
| RISPERDAL 3 mg film-coated tablets | DE/H/2184/005 | MA018/00202 | JANSSEN-CILAG INTERNATIONAL NV | MT |
| RISPERDAL 3 mg film-coated tablets | DE/H/2184/005 | PL 00242/0188 | JANSSEN-CILAG LIMITED | XI |
| Risperdal 3 mg filmdragerade tabletter | DE/H/2184/005 | 11994 | JANSSEN-CILAG AB | SE |
| RISPERDAL 3 mg filmomhulde tabletten | DE/H/2184/005 | BE165706 | JANSSEN-CILAG NV | BE |
| Risperdal 3 mg filmsko obložene tablete | DE/H/2184/005 | H/96/01358/020 | JOHNSON & JOHNSON D.O.O. | SI |
| RISPERDAL 3 mg Filmtabletten | DE/H/2184/005 | 1-20302 | JANSSEN-CILAG PHARMA GMBH | AT |
| Risperdal 3 mg Filmtabletten | DE/H/2184/005 | BE165706 | JANSSEN-CILAG NV | BE |
| Risperdal 3 mg Filmtabletten | DE/H/2184/005 | 2004058267 | JANSSEN-CILAG NV | LU |
| Risperdal 3 mg filmuhúðaðar töflur | DE/H/2184/005 | 920125 | JANSSEN-CILAG AB | IS |
| RISPERDAL 3 mg potahované tablety | DE/H/2184/005 | 68/185/95-C/C | JANSSEN-CILAG S.R.O | CZ |
| Risperdal 3 mg tabletter, filmdrasjerte | DE/H/2184/005 | 8039 | JANSSEN-CILAG A/S | NO |
| RISPERDAL 3 mg tabletti, kalvopäällysteinen | DE/H/2184/005 | 11480 | JANSSEN-CILAG OY | FI |
| RISPERDAL 3 mg επικαλυμμένα με λεπτό υμένιο δισκία | DE/H/2184/005 | 14398 | JANSSEN-CILAG INTERNATIONAL NV | CY |
| RISPERDAL 3 mg επικαλυμμένα με λεπτό υμένιο δισκία | DE/H/2184/005 | 111763/13-12-2017 | JANSSEN-CILAG PHARMACEUTICAL S.A.C.I. | GR |
| RISPERDAL 3 mg, filmomhulde tabletten | DE/H/2184/005 | RVG 16098 | JANSSEN-CILAG BV | NL |
| RISPERDAL 3 mg, Filmtabletten | DE/H/2184/005 | 28758.02.00 | JANSSEN-CILAG GMBH | DE |
| Risperdal 4 mg compresse rivestite con | DE/H/2184/006 | AIC 028752083 | JANSSEN-CILAG SPA | IT |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| film | | | | |
| Risperdal 4 mg compresse rivestite con film | DE/H/2184/006 | AIC 028752044 | JANSSEN-CILAG SPA | IT |
| RISPERDAL 4 mg comprimés pelliculés | DE/H/2184/006 | BE165715 | JANSSEN-CILAG NV | BE |
| RISPERDAL 4 mg comprimés pelliculés | DE/H/2184/006 | 2004058268 | JANSSEN-CILAG NV | LU |
| RISPERDAL 4 mg comprimidos revestidos por película | DE/H/2184/006 | 2306587 | JANSSEN FARMACÊUTICA PORTUGAL, LDA | PT |
| RISPERDAL 4 mg comprimidos revestidos por película | DE/H/2184/006 | 2306488 | JANSSEN FARMACÊUTICA PORTUGAL, LDA | PT |
| RISPERDAL 4 mg film-coated tablets | DE/H/2184/006 | PA22612/010/007 | JANSSEN SCIENCES IRELAND UC | IE |
| RISPERDAL 4 mg film-coated tablets | DE/H/2184/006 | PL 00242/0189 | JANSSEN-CILAG LIMITED | XI |
| Risperdal 4 mg filmdragerade tabletter | DE/H/2184/006 | 11995 | JANSSEN-CILAG AB | SE |
| RISPERDAL 4 mg filmomhulde tabletten | DE/H/2184/006 | BE165715 | JANSSEN-CILAG NV | BE |
| Risperdal 4 mg filmsko obložene tablete | DE/H/2184/006 | H/96/01358/024 | JOHNSON & JOHNSON D.O.O. | SI |
| RISPERDAL 4 mg Filmtabletten | DE/H/2184/006 | 1-20303 | JANSSEN-CILAG PHARMA GMBH | AT |
| Risperdal 4 mg Filmtabletten | DE/H/2184/006 | BE165715 | JANSSEN-CILAG NV | BE |
| Risperdal 4 mg Filmtabletten | DE/H/2184/006 | 2004058268 | JANSSEN-CILAG NV | LU |
| Risperdal 4 mg filmuhúðaðar töflur | DE/H/2184/006 | 920126 | JANSSEN-CILAG AB | IS |
| RISPERDAL 4 mg potahované tablety | DE/H/2184/006 | 68/185/95-D/C | JANSSEN-CILAG S.R.O | CZ |
| Risperdal 4 mg tabletter, filmdrasjerte | DE/H/2184/006 | 8040 | JANSSEN-CILAG A/S | NO |
| RISPERDAL 4 mg tabletti, | DE/H/2184/006 | 11481 | JANSSEN-CILAG OY | FI |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| kalvopäällysteinen | | | | |
| RISPERDAL 4 mg επικαλυμμένα με λεπτό υμένιο δισκία | DE/H/2184/006 | 14399 | JANSSEN-CILAG INTERNATIONAL NV | CY |
| RISPERDAL 4 mg επικαλυμμένα με λεπτό υμένιο δισκία | DE/H/2184/006 | 111764/13-12-2017 | JANSSEN-CILAG PHARMACEUTICAL S.A.C.I. | GR |
| RISPERDAL 4 mg, comprimé pelliculé | DE/H/2184/006 | 34009 338 953 0 3 | JANSSEN-CILAG | FR |
| RISPERDAL 4 mg, comprimé pelliculé | DE/H/2184/006 | 34009 338 954 7 1 | JANSSEN-CILAG | FR |
| RISPERDAL 4 mg, comprimé pelliculé | DE/H/2184/006 | 34009 344 273 8 1 | JANSSEN-CILAG | FR |
| RISPERDAL 4 mg, filmomhulde tabletten | DE/H/2184/006 | RVG 16099 | JANSSEN-CILAG BV | NL |
| RISPERDAL 4 mg, Filmtabletten | DE/H/2184/006 | 28758.03.00 | JANSSEN-CILAG GMBH | DE |
| RISPERDAL 6 mg comprimés pelliculés | DE/H/2184/007 | BE183881 | JANSSEN-CILAG NV | BE |
| RISPERDAL 6 mg comprimés pelliculés | DE/H/2184/007 | 2008089903 | JANSSEN-CILAG NV | LU |
| RISPERDAL 6 mg comprimidos recubiertos con película | DE/H/2184/007 | 62.803 | JANSSEN-CILAG S.A. | ES |
| RISPERDAL 6 mg film-coated tablets | DE/H/2184/007 | PA22612/010/002 | JANSSEN SCIENCES IRELAND UC | IE |
| RISPERDAL 6 mg film-coated tablets | DE/H/2184/007 | PL 00242/0317 | JANSSEN-CILAG LIMITED | XI |
| RISPERDAL 6 mg filmomhulde tabletten | DE/H/2184/007 | BE183881 | JANSSEN-CILAG NV | BE |
| RISPERDAL 6 mg Filmtabletten | DE/H/2184/007 | 1-22846 | JANSSEN-CILAG PHARMA GMBH | AT |
| Risperdal 6 mg Filmtabletten | DE/H/2184/007 | BE183881 | JANSSEN-CILAG NV | BE |
| Risperdal 6 mg Filmtabletten | DE/H/2184/007 | 2008089903 | JANSSEN-CILAG NV | LU |
| RISPERDAL 6 mg tabletti, | DE/H/2184/007 | 12302 | JANSSEN-CILAG OY | FI |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| kalvopäällysteinen | | | | |
| RISPERDAL 6 mg επικαλυμμένα με λεπτό υμένιο δισκία | DE/H/2184/007 | 111766/13-12-2017 | JANSSEN-CILAG PHARMACEUTICAL S.A.C.I. | GR |
| RISPERDAL 6 mg, Filmtabletten | DE/H/2184/007 | 37961.00.00 | JANSSEN-CILAG GMBH | DE |
| RISPERDAL CONSTA 25 mg powder and solvent for prolonged-release suspension for injection | DE/H/2184/013 | PL 00242/0375 | JANSSEN-CILAG LIMITED | XI |
| RISPERDAL CONSTA 25 mg pó e veículo para suspensão injetável de libertação prolongada | DE/H/2184/013 | 4753588 | JANSSEN FARMACÊUTICA PORTUGAL, LDA | PT |
| RISPERDAL CONSTA 25 mg polvo y disolvente para suspensión de liberación prolongada para inyección | DE/H/2184/013 | 65.213 | JANSSEN-CILAG S.A. | ES |
| Risperdal Consta 25 mg por és oldószer retard szuszpenziós injekcióhoz | DE/H/2184/013 | OGYI-T-8812/02 | JANSSEN-CILAG KFT. | HU |
| RISPERDAL CONSTA 25 mg poudre et solvant pour suspension injectable à libération prolongée | DE/H/2184/013 | BE254597 | JANSSEN-CILAG NV | BE |
| RISPERDAL CONSTA 25 mg poudre et solvant pour suspension injectable à libération prolongée | DE/H/2184/013 | 2004010026 | JANSSEN-CILAG NV | LU |
| RISPERDAL CONSTA 25 mg powder and solvent for prolonged-release suspension for injection | DE/H/2184/013 | PA22612/010/010 | JANSSEN SCIENCES IRELAND UC | IE |
| RISPERDAL CONSTA 25 | DE/H/2184/013 | MA018/00205 | JANSSEN-CILAG | MT |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| mg powder and solvent for prolonged-release suspension for injection | | | INTERNATIONAL NV | |
| Risperdal Consta 25 mg prašek in vehikel za suspenzijo s podaljšanim sproščanjem za injiciranje | DE/H/2184/013 | H/96/01358/001 | JOHNSON & JOHNSON D.O.O. | SI |
| Risperdal Consta 25 mg prašek in vehikel za suspenzijo s podaljšanim sproščanjem za injiciranje | DE/H/2184/013 | H/96/01358/030 | JOHNSON & JOHNSON D.O.O. | SI |
| RISPERDAL CONSTA 25 mg prášok a disperzné prostredie na injekčnú suspenziu s predĺženým uvoľňovaním | DE/H/2184/013 | 68/0105/03-S | JOHNSON & JOHNSON, S.R.O | SK |
| Risperdal Consta 25 mg pulver och vätska till injektionsvätska, depotsuspension | DE/H/2184/013 | 16894 | JANSSEN-CILAG OY | FI |
| Risperdal Consta 25 mg pulver och vätska till injektionsvätska, depotsuspension | DE/H/2184/013 | 17868 | JANSSEN-CILAG AB | SE |
| Risperdal Consta 25 mg pulver og væske til depotinjeksjonsvæske, suspensjon | DE/H/2184/013 | 01-9858 | JANSSEN-CILAG A/S | NO |
| RISPERDAL CONSTA 25 mg Pulver und Lösungsmittel zur Herstellung einer Depot-Injektionssuspension | DE/H/2184/013 | 52995.00.00 | JANSSEN-CILAG GMBH | DE |
| Risperdal Consta 25 mg Pulver und Lösungsmittel zur Herstellung einer Depot- | DE/H/2184/013 | BE254597 | JANSSEN-CILAG NV | BE |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| Injektionssuspension | | | | |
| Risperdal Consta 25 mg Pulver und Lösungsmittel zur Herstellung einer Depot-Injektionssuspension | DE/H/2184/013 | 2004010026 | JANSSEN-CILAG NV | LU |
| RISPERDAL CONSTA 25 mg Pulver und Lösungsmittel zur Herstellung einer verzögert freisetzenden Suspension zur Injektion | DE/H/2184/013 | 1-24628 | JANSSEN-CILAG PHARMA GMBH | AT |
| Risperdal Consta 25 mg stungulyfsstofn og leysir, forðadreifa | DE/H/2184/013 | IS/1/02/132/01 | JANSSEN-CILAG AB | IS |
| RISPERDAL CONSTA 25 mg κόνις και διαλύτης για παρασκευή ενέσιμου εναιωρήματος παρατεταμένης αποδέσμευσης | DE/H/2184/013 | 111767/13-12-2017 | JANSSEN-CILAG PHARMACEUTICAL S.A.C.I. | GR |
| RISPERDAL CONSTA 25 mg κόνις και διαλύτης για παρασκευή ενέσιμου εναιωρήματος παρατεταμένης αποδέσμευσης | DE/H/2184/013 | 19587 | JANSSEN-CILAG INTERNATIONAL NV | CY |
| RISPERDAL CONSTA 25 mg, poeder en oplosmiddel voor suspensie voor injectie met verlengde afgifte | DE/H/2184/013 | RVG 27178 | JANSSEN-CILAG BV | NL |
| RISPERDAL CONSTA 25 mg, prášek a rozpouštědlo pro injekční suspenzi s prodlouženým uvolňováním | DE/H/2184/013 | 68/068/03-C | JANSSEN-CILAG S.R.O | CZ |
| RISPERDAL CONSTA 37,5 mg pó e veículo | DE/H/2184/014 | 4753687 | JANSSEN FARMACÊUTICA PORTUGAL, LDA | PT |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| para suspensão injetável de libertação prolongada | | | | |
| RISPERDAL CONSTA 37,5 mg polvo y disolvente para suspensión de liberación prolongada para inyección | DE/H/2184/014 | 65.215 | JANSSEN-CILAG S.A. | ES |
| Risperdal Consta 37,5 mg por és oldószer retard szuszpenziós injekcióhoz | DE/H/2184/014 | OGYI-T-8812/04 | JANSSEN-CILAG KFT. | HU |
| RISPERDAL CONSTA 37,5 mg poudre et solvant pour suspension injectable à libération prolongée | DE/H/2184/014 | BE254606 | JANSSEN-CILAG NV | BE |
| RISPERDAL CONSTA 37,5 mg poudre et solvant pour suspension injectable à libération prolongée | DE/H/2184/014 | 2004010027 | JANSSEN-CILAG NV | LU |
| Risperdal Consta 37,5 mg prašek in vehikel za suspenzijo s podaljšanim sproščanjem za injiciranje | DE/H/2184/014 | H/96/01358/002 | JOHNSON & JOHNSON D.O.O. | SI |
| Risperdal Consta 37,5 mg prašek in vehikel za suspenzijo s podaljšanim sproščanjem za injiciranje | DE/H/2184/014 | H/96/01358/031 | JOHNSON & JOHNSON D.O.O. | SI |
| RISPERDAL CONSTA 37,5 mg prášok a disperzné prostredie na injekčnú suspenziu s predĺženým uvoľňovaním | DE/H/2184/014 | 68/0106/03-S | JOHNSON & JOHNSON, S.R.O | SK |
| Risperdal Consta 37,5 | DE/H/2184/014 | 16895 | JANSSEN-CILAG OY | FI |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| mg pulver och vätska till injektionsvätska, depotsuspension | | | | |
| Risperdal Consta 37,5 mg pulver och vätska till injektionsvätska, depotsuspension | DE/H/2184/014 | 17869 | JANSSEN-CILAG AB | SE |
| Risperdal Consta 37,5 mg pulver og væske til depotinjeksjonsvæske, suspensjon | DE/H/2184/014 | 01-9859 | JANSSEN-CILAG A/S | NO |
| RISPERDAL CONSTA 37,5 mg Pulver und Lösungsmittel zur Herstellung einer Depot-Injektionssuspension | DE/H/2184/014 | 52995.01.00 | JANSSEN-CILAG GMBH | DE |
| Risperdal Consta 37,5 mg Pulver und Lösungsmittel zur Herstellung einer Depot-Injektionssuspension | DE/H/2184/014 | BE254606 | JANSSEN-CILAG NV | BE |
| Risperdal Consta 37,5 mg Pulver und Lösungsmittel zur Herstellung einer Depot-Injektionssuspension | DE/H/2184/014 | 2004010027 | JANSSEN-CILAG NV | LU |
| RISPERDAL CONSTA 37,5 mg Pulver und Lösungsmittel zur Herstellung einer verzögert freisetzenden Suspension zur Injektion | DE/H/2184/014 | 1-24629 | JANSSEN-CILAG PHARMA GMBH | AT |
| Risperdal Consta 37,5 mg stungulyfsstofn og leysir, forðadreifa | DE/H/2184/014 | IS/1/02/132/02 | JANSSEN-CILAG AB | IS |
| RISPERDAL CONSTA 37,5 mg κόνις και διαλύτης για παρασκευή ενέσιμου εναιωρήματος | DE/H/2184/014 | 111768/13-12-2017 | JANSSEN-CILAG PHARMACEUTICAL S.A.C.I. | GR |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| παρατεταμένης αποδέσμευσης | | | | |
| RISPERDAL CONSTA 37,5 mg κόνις και διαλύτης για παρασκευή ενέσιμου εναιωρήματος παρατεταμένης αποδέσμευσης | DE/H/2184/014 | 19588 | JANSSEN-CILAG INTERNATIONAL NV | CY |
| RISPERDAL CONSTA 37,5 mg, poeder en oplosmiddel voor suspensie voor injectie met verlengde afgifte | DE/H/2184/014 | RVG 27179 | JANSSEN-CILAG BV | NL |
| RISPERDAL CONSTA 37,5 mg, prášek a rozpouštědlo pro injekční suspenzi s prodlouženým uvolňováním | DE/H/2184/014 | 68/069/03-C | JANSSEN-CILAG S.R.O | CZ |
| RISPERDAL CONSTA 37.5 mg powder and solvent for prolonged-release suspension for injection | DE/H/2184/014 | PA22612/010/011 | JANSSEN SCIENCES IRELAND UC | IE |
| RISPERDAL CONSTA 37.5 mg powder and solvent for prolonged-release suspension for injection | DE/H/2184/014 | MA018/00206 | JANSSEN-CILAG INTERNATIONAL NV | MT |
| RISPERDAL CONSTA 37.5 mg powder and solvent for prolonged-release suspension for injection | DE/H/2184/014 | PL 00242/0376 | JANSSEN-CILAG LIMITED | XI |
| RISPERDAL CONSTA 50 mg pó e veículo para suspensão de libertação prolongada para injecção intramuscular | DE/H/2184/015 | 4753786 | JANSSEN FARMACÊUTICA PORTUGAL, LDA | PT |
| RISPERDAL CONSTA 50 | DE/H/2184/015 | 65.214 | JANSSEN-CILAG S.A. | ES |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| mg polvo y disolvente para suspensión de liberación prolongada para inyección | | | | |
| Risperdal Consta 50 mg por és oldószer retard szuszpenziós injekcióhoz | DE/H/2184/015 | OGYI-T-8812/06 | JANSSEN-CILAG KFT. | HU |
| RISPERDAL CONSTA 50 mg poudre et solvant pour suspension injectable à libération prolongée | DE/H/2184/015 | BE254615 | JANSSEN-CILAG NV | BE |
| RISPERDAL CONSTA 50 mg poudre et solvant pour suspension injectable à libération prolongée | DE/H/2184/015 | 2004010028 | JANSSEN-CILAG NV | LU |
| RISPERDAL CONSTA 50 mg powder and solvent for prolonged-release suspension for injection | DE/H/2184/015 | PA22612/010/012 | JANSSEN SCIENCES IRELAND UC | IE |
| RISPERDAL CONSTA 50 mg powder and solvent for prolonged-release suspension for injection | DE/H/2184/015 | MA018/00207 | JANSSEN-CILAG INTERNATIONAL NV | MT |
| RISPERDAL CONSTA 50 mg powder and solvent for prolonged-release suspension for injection | DE/H/2184/015 | PL 00242/0377 | JANSSEN-CILAG LIMITED | XI |
| Risperdal Consta 50 mg prašek in vehikel za suspenzijo s podaljšanim sproščanjem za injiciranje | DE/H/2184/015 | H/96/01358/003 | JOHNSON & JOHNSON D.O.O. | SI |
| Risperdal Consta 50 mg prašek in vehikel za suspenzijo s podaljšanim sproščanjem za injiciranje | DE/H/2184/015 | H/96/01358/032 | JOHNSON & JOHNSON D.O.O. | SI |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| RISPERDAL CONSTA 50 mg prášok a disperzné prostredie na injekčnú suspenziu s predĺženým uvoľňovaním | DE/H/2184/015 | 68/0107/03-S | JOHNSON & JOHNSON, S.R.O | SK |
| Risperdal Consta 50 mg pulver och vätska till injektionsvätska, depotsuspension | DE/H/2184/015 | 16896 | JANSSEN-CILAG OY | FI |
| Risperdal Consta 50 mg pulver och vätska till injektionsvätska, depotsuspension | DE/H/2184/015 | 17870 | JANSSEN-CILAG AB | SE |
| Risperdal Consta 50 mg pulver og væske til depotinjeksjonsvæske, suspensjon | DE/H/2184/015 | 01-9860 | JANSSEN-CILAG A/S | NO |
| RISPERDAL CONSTA 50 mg Pulver und Lösungsmittel zur Herstellung einer Depot-Injektionssuspension | DE/H/2184/015 | 52995.02.00 | JANSSEN-CILAG GMBH | DE |
| Risperdal Consta 50 mg Pulver und Lösungsmittel zur Herstellung einer Depot-Injektionssuspension | DE/H/2184/015 | BE254615 | JANSSEN-CILAG NV | BE |
| Risperdal Consta 50 mg Pulver und Lösungsmittel zur Herstellung einer Depot-Injektionssuspension | DE/H/2184/015 | 2004010028 | JANSSEN-CILAG NV | LU |
| RISPERDAL CONSTA 50 mg Pulver und Lösungsmittel zur Herstellung einer verzögert freisetzenden Suspension zur Injektion | DE/H/2184/015 | 1-24630 | JANSSEN-CILAG PHARMA GMBH | AT |
| Risperdal Consta 50 mg | DE/H/2184/015 | IS/1/02/132/03 | JANSSEN-CILAG AB | IS |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| stungulyfsstofn og leysir, forðadreifa | | | | |
| RISPERDAL CONSTA 50 mg κόνις και διαλύτης για παρασκευή ενέσιμου εναιωρήματος παρατεταμένης αποδέσμευσης | DE/H/2184/015 | 111769/13-12-2017 | JANSSEN-CILAG PHARMACEUTICAL S.A.C.I. | GR |
| RISPERDAL CONSTA 50 mg κόνις και διαλύτης για παρασκευή ενέσιμου εναιωρήματος παρατεταμένης αποδέσμευσης | DE/H/2184/015 | 19589 | JANSSEN-CILAG INTERNATIONAL NV | CY |
| RISPERDAL CONSTA 50 mg, poeder en oplosmiddel voor suspensie voor injectie met verlengde afgifte | DE/H/2184/015 | RVG 27180 | JANSSEN-CILAG BV | NL |
| RISPERDAL CONSTA 50 mg, prášek a rozpouštědlo pro injekční suspenzi s prodlouženým uvolňováním | DE/H/2184/015 | 68/070/03-C | JANSSEN-CILAG S.R.O | CZ |
| Risperdal Consta, depotinjektionsvæske, pulver og solvens til suspension | DE/H/2184/013 | 33091 | JANSSEN-CILAG A/S | DK |
| Risperdal Consta, depotinjektionsvæske, pulver og solvens til suspension | DE/H/2184/014 | 33092 | JANSSEN-CILAG A/S | DK |
| Risperdal Consta, depotinjektionsvæske, pulver og solvens til suspension | DE/H/2184/015 | 33093 | JANSSEN-CILAG A/S | DK |
| RISPERDAL Lösung 1 mg/ml, Lösung zum Einnehmen | DE/H/2184/008 | 35950.00.00 | JANSSEN-CILAG GMBH | DE |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| RISPERDALCONSTA L.P. 25 mg/2 ml, poudre et solvant pour suspension injectable à libération prolongée en seringue préremplie | DE/H/2184/013 | 34009 362 491 3 4 | JANSSEN-CILAG | FR |
| RISPERDALCONSTA L.P. 37,5 mg/2 ml, poudre et solvant pour suspension injectable à libération prolongée en seringue préremplie | DE/H/2184/014 | 34009 362 493 6 3 | JANSSEN-CILAG | FR |
| RISPERDALCONSTA L.P. 50mg/2 ml, poudre et solvant pour suspension injectable à libération prolongée en seringue préremplie | DE/H/2184/015 | 34009 362 494 2 4 | JANSSEN-CILAG | FR |
| Risperidon - 1 A Pharma 0,25 mg Filmtabletten | DE/H/0923/001 | 67593.00.00 | 1 A PHARMA GMBH | DE |
| Risperidon - 1 A Pharma 0,5 mg Filmtabletten | DE/H/0793/001 | 66672.00.00 | 1 A PHARMA GMBH | DE |
| Risperidon - 1 A Pharma 6 mg Filmtabletten | DE/H/0923/002 | 67594.00.00 | 1 A PHARMA GMBH | DE |
| Risperidon 1A Pharma 0,5 mg - Filmtabletten | DE/H/0793/001 | 1-27040 | 1A PHARMA GMBH | AT |
| Risperidon HEXAL 0,25 mg Filmtabletten | DE/H/0922/001 | 67607.00.00 | HEXAL AG | DE |
| Risperidon Hexal 0,5 mg - Filmtabletten | DE/H/0792/001 | 1-27039 | HEXAL PHARMA GMBH | AT |
| Risperidon HEXAL 0,5 mg Filmtabletten | DE/H/0792/001 | 66671.00.00 | HEXAL AG | DE |
| Risperidon HEXAL 6 mg Filmtabletten | DE/H/0922/002 | 67608.00.00 | HEXAL AG | DE |
| Risperidon Sandoz 0,25 mg - Filmtabletten | DE/H/0924/001 | 1-27295 | SANDOZ GMBH | AT |
| Risperidon Sandoz 0,25 mg filmdragerad tablett | DE/H/0924/001 | 42117 | SANDOZ A/S | SE |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| Risperidon Sandoz 0,25 mg Filmtabletten | DE/H/0924/001 | 67727.00.00 | HEXAL AG | DE |
| Risperidon Sandoz 0,5 mg - Filmtabletten | DE/H/0794/001 | 1-27042 | SANDOZ GMBH | AT |
| Risperidon Sandoz 0,5 mg filmdragerade tabletter | DE/H/0794/001 | 24184 | SANDOZ A/S | SE |
| Risperidon Sandoz 0,5 mg Filmtabletten | DE/H/0794/001 | 66673.00.00 | HEXAL AG | DE |
| Risperidon Sandoz 0,5 mg tabletti, kalvopäällysteinen | DE/H/0794/001 | 22442 | SANDOZ A/S | FI |
| Risperidon Sandoz 6 mg Filmtabletten | DE/H/0924/002 | 67728.00.00 | HEXAL AG | DE |
| Risperidona Farmalider 0,5 mg comprimidos recubiertos con película. | not available | 66804 | FARMALIDER, S.A. | ES |
| Risperidona Farmalider 2 mg comprimidos recubiertos con película. | not available | 66805 | FARMALIDER, S.A. | ES |
| Risperidona Farmalider 4 mg comprimidos recubiertos con película. | not available | 66806 | FARMALIDER, S.A. | ES |
| Risperidone 0.25 mg film-coated tablet | not available | PL 25258/0236 | GLENMARK PHARMACEUTICALS EUROPE LIMITED | XI |
| Risperidone 0.25 mg film-coated tablets | not available | PL 17780/0955 | ZENTIVA PHARMA UK LIMITED | XI |
| Risperidone 1mg Tablets | FI/H/0373/001 | PL 04416/0662 | SANDOZ LTD | XI |
| Risperidone 2mg Tablets | FI/H/0373/002 | PL 04416/0663 | SANDOZ LTD | XI |
| Risperidone 3mg Tablets | FI/H/0373/003 | PL 04416/0664 | SANDOZ LTD | XI |
| Risperidone 4mg Tablets | FI/H/0373/004 | PL 04416/0665 | SANDOZ LTD | XI |
| Risperidone Aurobindo 0,5 mg compresse rivestite con film | NL/H/1957/001 | 040078014 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |
| Risperidone Aurobindo 0,5 mg compresse rivestite con film | NL/H/1957/001 | 040078026 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| Risperidone Aurobindo 0,5 mg compresse rivestite con film | NL/H/1957/001 | 040078038 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |
| Risperidone Aurobindo 0,5 mg compresse rivestite con film | NL/H/1957/001 | 040078040 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |
| Risperidone Aurobindo 0,5 mg compresse rivestite con film | NL/H/1957/001 | 040078053 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |
| Risperidone Aurobindo 0,5 mg compresse rivestite con film | NL/H/1957/001 | 040078065 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |
| Risperidone Aurobindo 0,5 mg compresse rivestite con film | NL/H/1957/001 | 040078077 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |
| Risperidone Aurobindo 0,5 mg compresse rivestite con film | NL/H/1957/001 | 040078089 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |
| Risperidone Aurobindo 0,5 mg compresse rivestite con film | NL/H/1957/001 | 040078091 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |
| Risperidone Aurobindo 0,5 mg compresse rivestite con film | NL/H/1957/001 | 040078103 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |
| Risperidone Aurobindo 0,5 mg compresse rivestite con film | NL/H/1957/001 | 040078584 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |
| Risperidone Aurobindo 0,5 mg compresse rivestite con film | NL/H/1957/001 | 040078596 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |
| Risperidone Aurobindo 4 mg film-coated tablets | PT/H/1467/004 | MA807/10304 | AUROBINDO PHARMA (MALTA) LIMITED | MT |
| Risperidone Aurobindo 6 mg compresse rivestite con film | NL/H/1957/006 | 040078519 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |
| Risperidone Aurobindo 6 mg compresse rivestite con film | NL/H/1957/006 | 040078521 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| Risperidone Aurobindo 6 mg compresse rivestite con film | NL/H/1957/006 | 040078533 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |
| Risperidone Aurobindo 6 mg compresse rivestite con film | NL/H/1957/006 | 040078545 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |
| Risperidone Aurobindo 6 mg compresse rivestite con film | NL/H/1957/006 | 040078558 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |
| Risperidone Aurobindo 6 mg compresse rivestite con film | NL/H/1957/006 | 040078560 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |
| Risperidone Aurobindo 6 mg compresse rivestite con film | NL/H/1957/006 | 040078572 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |
| RISPERIDONE EG 1 mg/ml, solution buvable | not available | NL32169 | EG LABO LABORATOIRES EUROGENERICS - DO NOT USE | FR |
| RISPERIDONE EG 1 mg/ml, solution buvable | not available | NL32169 | EG LABO LABORATOIRES EUROGENERICS - DO NOT USE | FR |
| Risperidone EG 8 mg comprimés pelliculés | not available | BE329813 | EUROGENERICS N.V./S.A. | BE |
| Risperidone EG 8 mg filmomhulde tabletten | not available | BE329813 | EUROGENERICS N.V./S.A. | BE |
| Risperidone EG 8 mg Filmtabletten | not available | BE329813 | EUROGENERICS N.V./S.A. | BE |
| Rispolept 1 mg apvalkotās tabletes | DE/H/2184/003 | 98-0099 | UAB "JOHNSON & JOHNSON" | LV |
| Rispolept 1 mg filmom obložene tablete | not available | HR-H-763047835 | JOHNSON & JOHNSON S.E. D.O.O. | HR |
| Rispolept 1 mg plėvele dengtos tabletės | DE/H/2184/003 | LT/1/96/0215/009 | UAB "JOHNSON & JOHNSON" | LT |
| Rispolept 1 mg plėvele dengtos tabletės | DE/H/2184/003 | LT/1/96/0215/002 | UAB "JOHNSON & JOHNSON" | LT |
| RISPOLEPT 1 mg, õhukese polümeerikattega | DE/H/2184/003 | 179497 | UAB "JOHNSON & JOHNSON" | EE |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| tabletid | | | | |
| Rispolept 1 mg/ml geriamasis tirpalas | DE/H/2184/008 | LT/1/98/0215/001 | UAB "JOHNSON & JOHNSON" | LT |
| Rispolept 1 mg/ml geriamasis tirpalas | DE/H/2184/008 | LT/1/98/0215/006 | UAB "JOHNSON & JOHNSON" | LT |
| Rispolept 1 mg/ml oralna otopina | not available | HR-H-242934497 | JOHNSON & JOHNSON S.E. D.O.O. | HR |
| Rispolept 1 mg/ml šķīdums iekšķīgai lietošanai | DE/H/2184/008 | 01-0372 | UAB "JOHNSON & JOHNSON" | LV |
| RISPOLEPT 1mg/ml soluţie orală | DE/H/2184/008 | 10489/2018/01 | JANSSEN PHARMACEUTICA NV | RO |
| RISPOLEPT 1mg/ml soluţie orală | DE/H/2184/008 | 10489/2018/03 | JANSSEN PHARMACEUTICA NV | RO |
| RISPOLEPT 1mg/ml soluţie orală | DE/H/2184/008 | 10489/2018/02 | JANSSEN PHARMACEUTICA NV | RO |
| RISPOLEPT 1mg/ml soluţie orală | DE/H/2184/008 | 10489/2018/04 | JANSSEN PHARMACEUTICA NV | RO |
| Rispolept 2 mg apvalkotās tabletes | DE/H/2184/004 | 98-0100 | UAB "JOHNSON & JOHNSON" | LV |
| Rispolept 2 mg filmom obložene tablete | not available | HR-H-223663247 | JOHNSON & JOHNSON S.E. D.O.O. | HR |
| Rispolept 2 mg plėvele dengtos tabletės | DE/H/2184/004 | LT/1/96/0215/014 | UAB "JOHNSON & JOHNSON" | LT |
| Rispolept 2 mg plėvele dengtos tabletės | DE/H/2184/004 | LT/1/96/0215/003 | UAB "JOHNSON & JOHNSON" | LT |
| RISPOLEPT 2 mg, õhukese polümeerikattega tabletid | DE/H/2184/004 | 179597 | UAB "JOHNSON & JOHNSON" | EE |
| Rispolept 3 mg apvalkotās tabletes | DE/H/2184/005 | 98-0101 | UAB "JOHNSON & JOHNSON" | LV |
| Rispolept 3 mg filmom obložene tablete | not available | HR-H-502104199 | JOHNSON & JOHNSON S.E. D.O.O. | HR |
| Rispolept 3 mg plėvele dengtos tabletės | DE/H/2184/005 | LT/1/96/0215/019 | UAB "JOHNSON & JOHNSON" | LT |
| Rispolept 3 mg plėvele dengtos tabletės | DE/H/2184/005 | LT/1/96/0215/004 | UAB "JOHNSON & JOHNSON" | LT |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| RISPOLEPT 3 mg, õhukese polümeerikattega tabletid | DE/H/2184/005 | 179697 | UAB "JOHNSON & JOHNSON" | EE |
| Rispolept 4 mg apvalkotās tabletes | DE/H/2184/006 | 98-0102 | UAB "JOHNSON & JOHNSON" | LV |
| Rispolept 4 mg filmom obložene tablete | not available | HR-H-410432880 | JOHNSON & JOHNSON S.E. D.O.O. | HR |
| Rispolept 4 mg plėvele dengtos tabletės | DE/H/2184/006 | LT/1/96/0215/022 | UAB "JOHNSON & JOHNSON" | LT |
| Rispolept 4 mg plėvele dengtos tabletės | DE/H/2184/006 | LT/1/96/0215/005 | UAB "JOHNSON & JOHNSON" | LT |
| RISPOLEPT 4 mg, õhukese polümeerikattega tabletid | DE/H/2184/006 | 179797 | UAB "JOHNSON & JOHNSON" | EE |
| RISPOLEPT CONSTA 25 mg milteliai ir tirpiklis pailginto atpalaidavimo injekcinei suspensijai | DE/H/2184/013 | LT/1/03/3651/001 | UAB "JOHNSON & JOHNSON" | LT |
| Rispolept Consta 25 mg prašak i otapalo za suspenziju za injekciju s produljenim oslobađanjem | not available | HR-H-137353036 | JOHNSON & JOHNSON S.E. D.O.O. | HR |
| RISPOLEPT CONSTA 25 mg pulbere şi solvent pentru suspensie injectabilă cu eliberare prelungită | DE/H/2184/013 | 10490/2018/01 | JANSSEN PHARMACEUTICA NV | RO |
| RISPOLEPT CONSTA 25 mg pulbere şi solvent pentru suspensie injectabilă cu eliberare prelungită | DE/H/2184/013 | 10490/2018/02 | JANSSEN PHARMACEUTICA NV | RO |
| RISPOLEPT CONSTA 25 mg pulveris un šķīdinātājs ilgstošas | DE/H/2184/013 | 03-0096 | UAB "JOHNSON & JOHNSON" | LV |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| darbības injekciju suspensijas pagatavošanai | | | | |
| RISPOLEPT CONSTA 25 mg, toimeainet prolongeeritult vabastava süstesuspensiooni pulber ja lahusti | DE/H/2184/013 | 410603 | UAB "JOHNSON & JOHNSON" | EE |
| RISPOLEPT CONSTA 37 mg pulbere şi solvent pentru suspensie injectabilă cu eliberare prelungită | DE/H/2184/014 | 10491/2018/02 | JANSSEN PHARMACEUTICA NV | RO |
| RISPOLEPT CONSTA 37,5 mg milteliai ir tirpiklis pailginto atpalaidavimo injekcinei suspensijai | DE/H/2184/014 | LT/1/03/3651/002 | UAB "JOHNSON & JOHNSON" | LT |
| Rispolept Consta 37,5 mg prašak i otapalo za suspenziju za injekciju s produljenim oslobađanjem | not available | HR-H-257884610 | JOHNSON & JOHNSON S.E. D.O.O. | HR |
| RISPOLEPT CONSTA 37,5 mg pulbere şi solvent pentru suspensie injectabilă cu eliberare prelungită | DE/H/2184/014 | 10491/2018/01 | JANSSEN PHARMACEUTICA NV | RO |
| RISPOLEPT CONSTA 37,5 mg pulveris un šķīdinātājs ilgstošas darbības injekciju suspensijas pagatavošanai | DE/H/2184/014 | 03-0097 | UAB "JOHNSON & JOHNSON" | LV |
| RISPOLEPT CONSTA 37,5 mg, toimeainet prolongeeritult vabastava | DE/H/2184/014 | 410703 | UAB "JOHNSON & JOHNSON" | EE |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| süstesuspensiooni pulber ja lahusti | | | | |
| RISPOLEPT CONSTA 50 mg milteliai ir tirpiklis pailginto atpalaidavimo injekcinei suspensijai | DE/H/2184/015 | LT/1/03/3651/003 | UAB "JOHNSON & JOHNSON" | LT |
| Rispolept Consta 50 mg prašak i otapalo za suspenziju za injekciju s produljenim oslobađanjem | not available | HR-H-805764530 | JOHNSON & JOHNSON S.E. D.O.O. | HR |
| RISPOLEPT CONSTA 50 mg pulbere şi solvent pentru suspensie injectabilă cu eliberare prelungită | DE/H/2184/015 | 10492/2018/01 | JANSSEN PHARMACEUTICA NV | RO |
| RISPOLEPT CONSTA 50 mg pulbere şi solvent pentru suspensie injectabilă cu eliberare prelungită | DE/H/2184/015 | 10492/2018/02 | JANSSEN PHARMACEUTICA NV | RO |
| RISPOLEPT CONSTA 50 mg pulveris un šķīdinātājs ilgstošas darbības injekciju suspensijas pagatavošanai | DE/H/2184/015 | 03-0098 | UAB "JOHNSON & JOHNSON" | LV |
| RISPOLEPT CONSTA 50 mg, toimeainet prolongeeritult vabastava süstesuspensiooni pulber ja lahusti | DE/H/2184/015 | 410803 | UAB "JOHNSON & JOHNSON" | EE |
| Rispolept Consta, 25 mg, proszek i rozpuszczalnik do sporządzania zawiesiny do wstrzykiwań o przedłużonym | DE/H/2184/013 | 10582 | JANSSEN-CILAG INTERNATIONAL NV | PL |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| uwalnianiu. | | | | |
| Rispolept Consta, 37,5 mg, proszek i rozpuszczalnik do sporządzania zawiesiny do wstrzykiwań o przedłużonym uwalnianiu. | DE/H/2184/014 | 10581 | JANSSEN-CILAG INTERNATIONAL NV | PL |
| Rispolept Consta, 50 mg, proszek i rozpuszczalnik do sporządzania zawiesiny do wstrzykiwań o przedłużonym uwalnianiu | DE/H/2184/015 | 10580 | JANSSEN-CILAG INTERNATIONAL NV | PL |
| Rispolept, 1 mg, tabletki powlekane | DE\H\2184\003 | R/6704 | JANSSEN-CILAG INTERNATIONAL NV | PL |
| Rispolept, 1 mg, tabletki powlekane | DE/H/2184/003 | R/6704 | JANSSEN-CILAG INTERNATIONAL NV | PL |
| RISPOLEPT, 1 mg/ml suukaudne lahus | DE/H/2184/008 | 273799 | UAB "JOHNSON & JOHNSON" | EE |
| Rispolept, 1 mg/ml, roztwór doustny | DE/H/2184/008 | 4238 | JANSSEN-CILAG INTERNATIONAL NV | PL |
| Rispolept, 2 mg, tabletki powlekane | DE/H/2184/004 | R/6705 | JANSSEN-CILAG INTERNATIONAL NV | PL |
| Rispolept, 3 mg, tabletki powlekane | DE/H/2184/005 | R/6706 | JANSSEN-CILAG INTERNATIONAL NV | PL |
| Rispolept, 4 mg, tabletki powlekane | DE/H/2184/006 | R/6707 | JANSSEN-CILAG INTERNATIONAL NV | PL |