



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2018
EMA/765809/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: dapoxetine

Procedure no.: PSUSA/00000928/201712



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
Priligy 30 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/0718/001	21464	MENARINI HELLAS PHARMACEUTICAL S.A	CY
Priligy 60 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/0718/002	21465	MENARINI HELLAS PHARMACEUTICAL S.A	CY
Priligy 30 mg filmom obložene tablete	SE/H/0718/001	HR-H-674827417	BERLIN-CHEMIE AG	HR
Priligy 30 mg filmom obložene tablete	SE/H/0718/001	HR-H-674827417	BERLIN-CHEMIE AG	HR
Priligy 60 mg filmom obložene tablete	SE/H/0718/002	HR-H-635589393-03	BERLIN-CHEMIE AG	HR
Priligy 60 mg filmom obložene tablete	SE/H/0718/002	HR-H-635589393	BERLIN-CHEMIE AG	HR
Priligy 60 mg filmom obložene tablete	SE/H/0718/002	HR-H-635589393	BERLIN-CHEMIE AG	HR
Priligy 60 mg filmom obložene tablete	SE/H/0718/002	HR-H-635589393	BERLIN-CHEMIE AG	HR
Priligy 30 mg filmom obložene tablete	SE/H/0718/001	HR-H-674827417	BERLIN-CHEMIE AG	HR

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
Priligy 30 mg filmom obložene tablete	SE/H/0718/001	HR-H-674827417	BERLIN-CHEMIE AG	HR
Priligy 30 mg Filmtabletten	SE/H/0718/001	BE422387	MENARINI BENELUX N.V./S.A.	BE
Priligy 30 mg comprimés pelliculés	SE/H/0718/001	BE422387	MENARINI BENELUX N.V./S.A.	BE
Priligy 60 mg Filmtabletten	SE/H/0718/002	BE422396	MENARINI BENELUX N.V./S.A.	BE
Priligy 60 mg comprimés pelliculés	SE/H/0718/002	BE422396	MENARINI BENELUX N.V./S.A.	BE
Priligy 30 mg filmdragerade tabletter	SE/H/0718/001	24353	BERLIN-CHEMIE AG	FI
Priligy 60 mg filmdragerade tabletter	SE/H/0718/002	24354	BERLIN-CHEMIE AG	FI
Priligy 60 mg filmsko obložene tablete	SE/H/0718/002	H/12/01284/006	BERLIN-CHEMIE AG	SI
Priligy 30 mg filmsko obložene tablete	SE/H/0718/001	H/12/01284/002	BERLIN-CHEMIE AG	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
Priligy 60 mg filmsko obložene tablete	SE/H/0718/002	H/12/01284/005	BERLIN-CHEMIE AG	SI
Priligy 30 mg filmsko obložene tablete	SE/H/0718/001	H/12/01284/003	BERLIN-CHEMIE AG	SI
Priligy 60 mg filmsko obložene tablete	SE/H/0718/002	H/12/01284/007	BERLIN-CHEMIE AG	SI
Priligy 30 mg filmsko obložene tablete	SE/H/0718/001	H/12/01284/001	BERLIN-CHEMIE AG	SI
Priligy 30 mg comprimate filmate	SE/H/0718/001	7473/2015/01	BERLIN-CHEMIE AG	RO
Priligy 60 mg comprimate filmate	SE/H/0718/002	7474/2015/01	BERLIN-CHEMIE AG	RO
Priligy 60 mg comprimate filmate	SE/H/0718/002	7474/2015/04	BERLIN-CHEMIE AG	RO
Priligy 30 mg comprimate filmate	SE/H/0718/001	7473/2015/04	BERLIN-CHEMIE AG	RO
Priligy 30 mg comprimate filmate	SE/H/0718/001	7473/2015/02	BERLIN-CHEMIE AG	RO

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
Priligy 60 mg comprimate filmate	SE/H/0718/002	7474/2015/03	BERLIN-CHEMIE AG	RO
Priligy 30 mg comprimate filmate	SE/H/0718/001	7473/2015/03	BERLIN-CHEMIE AG	RO
Priligy 60 mg comprimate filmate	SE/H/0718/002	7474/2015/02	BERLIN-CHEMIE AG	RO
Priligy 30 mg filmsko obložene tablete	SE/H/0718/001	H/12/01284/004	BERLIN-CHEMIE AG	SI
Priligy 60 mg filmsko obložene tablete	SE/H/0718/002	H/12/01284/008	BERLIN-CHEMIE AG	SI
Priligy 30 mg Filmtabletten	SE/H/0718/001	1-28010	BERLIN-CHEMIE AG	AT
Priligy 60 mg Filmtabletten	SE/H/0718/002	1-28011	BERLIN-CHEMIE AG	AT
Priligy 60 mg filmomhulde tabletten	SE/H/0718/002	BE422396	MENARINI BENELUX N.V./S.A.	BE
Priligy 30 mg filmomhulde tabletten	SE/H/0718/001	BE422387	MENARINI BENELUX N.V./S.A.	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
Priligy 60 mg comprimidos recubiertos con película	SE/H/0718/002	70.875	LABORATORIOS MENARINI, S.A.	ES
Priligy 30 mg comprimidos recubiertos con película	SE/H/0718/001	70.874	LABORATORIOS MENARINI, S.A.	ES
Priligy 30 mg potahované tablety	SE/H/0718/001	87/315/12-C	BERLIN-CHEMIE AG	CZ
Priligy, 60 mg õhukese polümeerikattega tabletid	SE/H/0718/002	778412	BERLIN-CHEMIE AG	EE
Priligy 60 mg potahované tablety	SE/H/0718/002	87/316/12-C	BERLIN-CHEMIE AG	CZ
Priligy, 30 mg õhukese polümeerikattega tabletid	SE/H/0718/001	778312	BERLIN-CHEMIE AG	EE
Priligy 60 mg filmtabletta	SE/H/0718/002	OGYI-T-22140/08	BERLIN-CHEMIE AG	HU
PRILIGY 30 mg comprimé pelliculé	SE/H/0718/001	34009 222 690 3 0	MENARINI FRANCE	FR
Priligy 30 mg filmtabletta	SE/H/0718/001	OGYI-T-22140/02	BERLIN-CHEMIE AG	HU

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
Priligy 60 mg filmtabletta	SE/H/0718/002	OGYI-T-22140/06	BERLIN-CHEMIE AG	HU
Priligy 60 mg filmtabletta	SE/H/0718/002	OGYI-T-22140/07	BERLIN-CHEMIE AG	HU
Priligy 30 mg filmtabletta	SE/H/0718/001	OGYI-T-22140/01	BERLIN-CHEMIE AG	HU
Priligy 30 mg filmtabletta	SE/H/0718/001	OGYI-T-22140/04	BERLIN-CHEMIE AG	HU
PRILIGY 60 mg, comprimé pelliculé	SE/H/0718/002	34009 222 697 8 8	MENARINI FRANCE	FR
Priligy 30 mg compresse rivestite con film	SE/H/0718/001	039041013	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
Priligy 60 mg Filmtabletten	SE/H/0718/002	71670.00.00	BERLIN-CHEMIE AG	DE
PRILIGY 30 mg comprimé pelliculé	SE/H/0718/001	34009 222 692 6 9	MENARINI FRANCE	FR
Priligy 30 mg compresse rivestite con film	SE/H/0718/001	039041064	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - 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
Priligy 30 mg compresse rivestite con film	SE/H/0718/001	039041052	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
PRILIGY 60 mg, comprimé pelliculé	SE/H/0718/002	34009 222 694 9 8	MENARINI FRANCE	FR
PRILIGY 30 mg comprimé pelliculé	SE/H/0718/001	34009 222 693 2 0	MENARINI FRANCE	FR
Priligy 30 mg filmtabletta	SE/H/0718/001	OGYI-T-22140/03	BERLIN-CHEMIE AG	HU
PRILIGY 30 mg comprimé pelliculé	SE/H/0718/001	34009 222 689 5 8	MENARINI FRANCE	FR
PRILIGY 60 mg, comprimé pelliculé	SE/H/0718/002	34009 222 695 5 9	MENARINI FRANCE	FR
PRILIGY 60 mg, comprimé pelliculé	SE/H/0718/002	34009 222 696 1 0	MENARINI FRANCE	FR
Priligy 30 mg compresse rivestite con film	SE/H/0718/001	039041025	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
Priligy 60 mg compresse rivestite con film	SE/H/0718/002	039041037	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - 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
Priligy 60 mg compresse rivestite con film	SE/H/0718/002	039041076	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
Priligy 60 mg filmtabletta	SE/H/0718/002	OGYI-T-22140/05	BERLIN-CHEMIE AG	HU
Priligy 30 mg Filmtabletten	SE/H/0718/001	71669.00.00	BERLIN-CHEMIE AG	DE
Priligy 60 mg compresse rivestite con film	SE/H/0718/002	039041049	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
Priligy 60 mg compresse rivestite con film	SE/H/0718/002	039041088	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
Priligy 30 mg filmomhulde tabletten	SE/H/0718/001	RVG 108199	MENARINI BENELUX N.V./S.A.	NL
Priligy 60 mg filmomhulde tabletten	SE/H/0718/002	RVG 108200	MENARINI BENELUX N.V./S.A.	NL
Priligy 30 mg plėvele dengtos tabletės	SE/H/0718/001	LT/1/12/2920/001	BERLIN-CHEMIE AG	LT
Priligy 30 mg plėvele dengtos tabletės	SE/H/0718/001	LT/1/12/2920/002	BERLIN-CHEMIE AG	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
Priligy 60 mg plēvele dengtos tabletēs	SE/H/0718/002	LT/1/12/2920/007	BERLIN-CHEMIE AG	LT
Priligy 30 mg plēvele dengtos tabletēs	SE/H/0718/001	LT/1/12/2920/003	BERLIN-CHEMIE AG	LT
Priligy 30 mg apvalkotās tabletes	SE/H/0718/001	12-0095	BERLIN-CHEMIE AG	LV
Priligy 60 mg apvalkotās tabletes	SE/H/0718/002	12-0096	BERLIN-CHEMIE AG	LV
Priligy 30 mg plēvele dengtos tabletēs	SE/H/0718/001	LT/1/12/2920/004	BERLIN-CHEMIE AG	LT
Priligy 60 mg plēvele dengtos tabletēs	SE/H/0718/002	LT/1/12/2920/005	BERLIN-CHEMIE AG	LT
Priligy 60 mg plēvele dengtos tabletēs	SE/H/0718/002	LT/1/12/2920/006	BERLIN-CHEMIE AG	LT
Priligy, 60 mg, tabletki powlekane	SE/H/0718/002	20413	BERLIN-CHEMIE AG	PL
Priligy, 30 mg, tabletki powlekane	SE/H/0718/001	20412	BERLIN-CHEMIE AG	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
Priligy 60 mg plévele dengtos tabletés	SE/H/0718/002	LT/1/12/2920/008	BERLIN-CHEMIE AG	LT
Priligy 60 mg comprimidos revestidos por película	SE/H/0718/002	5178249	A. MENARINI PORTUGAL, FARMACÊUTICA, S.A.	PT
Priligy 30 mg comprimidos revestidos por película	SE/H/0718/001	5178215	A. MENARINI PORTUGAL, FARMACÊUTICA, S.A.	PT
Priligy 60 mg comprimidos revestidos por película	SE/H/0718/002	5178231	A. MENARINI PORTUGAL, FARMACÊUTICA, S.A.	PT
Priligy 30 mg comprimidos revestidos por película	SE/H/0718/001	5178223	A. MENARINI PORTUGAL, FARMACÊUTICA, S.A.	PT
Priligy 30 mg filmom obalené tablety	SE/H/0718/001	87/0117/12-S	BERLIN-CHEMIE AG	SK
Priligy 60 mg filmom obalené tablety	SE/H/0718/002	87/0118/12-S	BERLIN-CHEMIE AG	SK
Priligy 60 mg comprimés pelliculés	SE/H/0718/002	2013040122	MENARINI BENELUX N.V./S.A.	LU
Priligy 30 mg comprimés pelliculés	SE/H/0718/001	2013040121	MENARINI BENELUX N.V./S.A.	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
Priligy 60 mg film-coated tablets	SE/H/0718/002	PA 1833/1/2	A. MENARINI PHARMACEUTICALS IRELAND LIMITED	IE
Priligy 60 mg film-coated tablets	SE/H/0718/002	PL 41549/0002	A. MENARINI FARMACEUTICA INTERNAZIONALE SRL-UK BRANCH	UK
Priligy 30 mg film-coated tablets	SE/H/0718/001	PL 41549/0001	A. MENARINI FARMACEUTICA INTERNAZIONALE SRL-UK BRANCH	UK
Priligy 30 mg film-coated tablets	SE/H/0718/001	PA 1833/1/1	A. MENARINI PHARMACEUTICALS IRELAND LIMITED	IE
Прилижи 60 mg филмирани таблетки	SE/H/0718/002	20120183	BERLIN-CHEMIE AG	BG
Прилижи 30 mg филмирани таблетки	SE/H/0718/001	20120182	BERLIN-CHEMIE AG	BG
Priligy 30 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/0718/001	51670	MENARINI HELLAS PHARMACEUTICAL S.A	GR
Priligy 60 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/0718/002	51671	MENARINI HELLAS PHARMACEUTICAL S.A	GR
Priligy 30 mg filmdragerade tabletter	SE/H/0718/001	26319	BERLIN-CHEMIE AG	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
Priligy 60 mg filmdragerade tabletter	SE/H/0718/002	26320	BERLIN-CHEMIE AG	SE
Priligy, filmovertrukne tabletter	SE/H/0718/001	47473	BERLIN-CHEMIE AG	DK
Priligy 60 mg kalvopäällysteiset tabletit	SE/H/0718/002	24354	BERLIN-CHEMIE AG	FI
Priligy 30 mg kalvopäällysteiset tabletit	SE/H/0718/001	24353	BERLIN-CHEMIE AG	FI
Priligy, filmovertrukne tabletter	SE/H/0718/002	47474	BERLIN-CHEMIE AG	DK
Priligy 30 mg filmuhúðaðar töflur	SE/H/0718/001	IS/1/12/012/01	BERLIN-CHEMIE AG	IS
Priligy 60 mg filmuhúðaðar töflur	SE/H/0718/002	IS/1/12/012/02	BERLIN-CHEMIE AG	IS
Priligy 30 mg filmdrasjerte tabletter	SE/H/0718/001	10-7834	BERLIN-CHEMIE AG	NO
Priligy 60 mg filmdrasjerte tabletter	SE/H/0718/002	10-7835	BERLIN-CHEMIE AG	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
Priligy 30 mg film-coated tablets	SE/H/0718/001	MA1022/00101	A. MENARINI PHARMACEUTICALS IRELAND LIMITED	MT
Priligy 60 mg film-coated tablets	SE/H/0718/002	MA1022/00102	A. MENARINI PHARMACEUTICALS IRELAND LIMITED	MT