



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 August 2023
EMA/141568/2024
Pharmacovigilance Risk Assessment Committee (PRAC)

List of nationally authorised medicinal products

Active substance(s): felodipine

Procedure no.: PSUSA/00001356/202212



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
Prevex 5 mg compresse a rilascio prolungato	SE/H/1506/002	027372046	SIMESA S.P.A.	IT
Prevex 5 mg compresse a rilascio prolungato	SE/H/1506/002	027372061	SIMESA S.P.A.	IT
Prevex 5 mg compresse a rilascio prolungato	SE/H/1506/002	027372059	SIMESA S.P.A.	IT
Prevex 5 mg compresse a rilascio prolungato	SE/H/1506/002	027372073	SIMESA S.P.A.	IT
Prevex 10 mg compresse a rilascio prolungato	SE/H/1506/003	027372085	SIMESA S.P.A.	IT
Prevex 10 mg compresse a rilascio prolungato	SE/H/1506/003	027372097	SIMESA S.P.A.	IT
Prevex 5 mg compresse a rilascio prolungato	SE/H/1506/002	027372010	SIMESA S.P.A.	IT
Prevex 10 mg compresse a rilascio prolungato	SE/H/1506/003	027372034	SIMESA S.P.A.	IT
Prevex 10 mg compresse a rilascio prolungato	SE/H/1506/003	027372022	SIMESA S.P.A.	IT
PLENDIL 10 mg comprimate cu eliberare prelungită	SE/H/1505/003	7360/2015/01	ASTRAZENECA AB	RO
PLENDIL 2,5 mg comprimate cu eliberare prelungită	SE/H/1505/001	7358/2015/01	ASTRAZENECA AB	RO
Plendil 5 mg, comprimate cu eliberare prelungită	SE/H/1505/002	7359/2015/01	ASTRAZENECA AB	RO
PLENDIL 10 mg Retard, comprimés à libération prolongée	SE/H/1505/003	BE141644	ASTRAZENECA S.A. / N.V.	BE
Plendil 10 mg Retard, tabletten met verlengde afgifte	SE/H/1505/003	BE141644	ASTRAZENECA S.A. / N.V.	BE
Plendil ER 10 mg tablety s prodlouženým uvolňováním	SE/H/1505/003	83/115/92-C/C	ASTRAZENECA AB	CZ
Plendil, 10 mg toimeainet prolongeeritult vabastav tablett	SE/H/1505/003	146796	ASTRAZENECA AB	EE
Plendil 10 mg depottabletti	SE/H/1505/003	10338	ASTRAZENECA OY	FI
Modip® 10 mg, Retardtabletten	SE/H/1505/003	11310.00.00	ASTRAZENECA 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
PLENDIL 10 mg Retard, comprimés à libération prolongée	SE/H/1505/003	BE236686	ASTRAZENECA S.A. / N.V.	BE
Plendil 10 mg Retard, tabletten met verlengde afgifte	SE/H/1505/003	BE236686	ASTRAZENECA S.A. / N.V.	BE
Plendil 10 mg compresse a rilascio prolungato	SE/H/1505/003	028162030	ASTRAZENECA S.P.A.	IT
Plendil 10 mg δισκία παρατεταμένης αποδέσμευσης	SE/H/1505/003	8492 / 06-02-2007	ASTRAZENECA S.A	GR
Plendil 10 mg δισκία παρατεταμένης αποδέσμευσης	SE/H/1505/003	12025	ASTRAZENECA AB	CY
Plendil 10 mg prolonged-release tablets	SE/H/1505/003	PA 1019/016/003	ASTRAZENECA AB	IE
PLENDIL 10 mg Retard, comprimés à libération prolongée	SE/H/1505/003	0173/04118587	ASTRAZENECA S.A. / N.V.	LU
Plendil, 10 mg, tabletki o przedłużonym uwalnianiu	SE/H/1505/003	R/3449	ASTRAZENECA AB	PL
PLENDIL 10 mg depottabletter	SE/H/1505/003	10733	ASTRAZENECA AB	SE
Plendil, 2,5 mg toimeainet prolongeeritult vabastav tablett	SE/H/1505/001	165697	ASTRAZENECA AB	EE
Plendil 2,5 mg depottabletti	SE/H/1505/001	10959	ASTRAZENECA OY	FI
Plendil 2,5 mg δισκία παρατεταμένης αποδέσμευσης	SE/H/1505/001	19573	ASTRAZENECA AB	CY
Plendil retard 2,5 mg - Filmtabletten	SE/H/1505/001	1-20.523	ASTRAZENECA OSTERREICH GMBH	AT
Plendil 2,5 mg δισκία παρατεταμένης αποδέσμευσης	SE/H/1505/001	8492/06-02-2007	ASTRAZENECA S.A	GR
Plendil 2,5, tabletten met verlengde afgifte 2,5 mg	SE/H/1505/001	RVG 15580	ASTRAZENECA BV	NL
Plendil 2.5mg prolonged release tablets	SE/H/1505/001	PA 1019/016/001	ASTRAZENECA AB	IE
PLENDIL 2,5 mg depottabletter	SE/H/1505/001	11442	ASTRAZENECA AB	SE
PLENDIL 5 mg Retard, tabletten met verlengde afgifte	SE/H/1505/002	BE141251	ASTRAZENECA S.A. / N.V.	BE
Plendil retard 5 mg - Filmtabletten	SE/H/1505/002	1-18766	ASTRAZENECA OSTERREICH GMBH	AT
PLENDIL 5 mg Retard, comprimés à	SE/H/1505/002	BE141251	ASTRAZENECA S.A. / N.V.	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
libération prolongée				
Plendil 5 mg δισκία παρατεταμένης αποδέσμευσης	SE/H/1505/002	12026	ASTRAZENECA AB	CY
Плендил 5 mg таблетки с удължено освобождаване	SE/H/1505/002	9900022	ASTRAZENECA AB	BG
Plendil ER 5 mg tablety s prodlouženým uvolňováním	SE/H/1505/002	83/115/92-B/C	ASTRAZENECA AB	CZ
Plendil 5 mg depottabletti	SE/H/1505/002	10337	ASTRAZENECA OY	FI
Plendil, 5 mg toimeainet prolongeeritult vabastav tablett	SE/H/1505/002	146696	ASTRAZENECA AB	EE
Plendil 5 mg δισκία παρατεταμένης αποδέσμευσης	SE/H/1505/002	8492/06-02-2007	ASTRAZENECA S.A	GR
FLODIL L.P. 5 mg, comprimé enrobé à libération prolongée	SE/H/1505/002	3400933285340	ASTRAZENECA S.A.S.	FR
Modip® 5 mg, Retardtabletten	SE/H/1505/002	11310.01.00	ASTRAZENECA GMBH	DE
Plendil 5 mg compresse a rilascio prolungato	SE/H/1505/002	028162042	ASTRAZENECA S.P.A.	IT
Plendil 5 mg prolonged-release tablets	SE/H/1505/002	PA 1019/016/002	ASTRAZENECA AB	IE
PLENDIL 5 mg Retard, comprimés à libération prolongée	SE/H/1505/002	0173/04118586	ASTRAZENECA S.A. / N.V.	LU
Plendil 5 mg comprimidos de liberación prolongada	SE/H/1505/002	59.269	LABORATORIO BETA S.A.	ES
PLENDIL 5 mg depottabletter	SE/H/1505/002	10732	ASTRAZENECA AB	SE
Plendil, 5 mg, tabletki o przedłużonym uwalnianiu	SE/H/1505/002	R/3448	ASTRAZENECA AB	PL
Plendil 5mg Prolonged-release, Film-coated Tablets	SE/H/1505/002	MA 046/00201	ASTRAZENECA AB	MT
Plendil 5 mg tablety s predĺženým uvolňovaním	SE/H/1505/002	83/0545/12-S	ASTRAZENECA AB	SK
Plendil 10 mg depottabletter	SE/H/1505/003	7572	ASTRAZENECA AS	NO
Plendil 5 mg depottabletter	SE/H/1505/002	7571	ASTRAZENECA AS	NO
Plendil 2,5 mg depottabletter	SE/H/1505/001	7833	ASTRAZENECA AS	NO
Plendil 5 mg tablete s produljenim oslobađanjem	SE/H/1505/002	HR-H-597365768-03	ASTRAZENECA D.O.O.	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
Plendil 5 mg tablete s produljenim oslobađanjem	SE/H/1505/002	HR-H-597365768-04	ASTRAZENECA D.O.O.	HR
Plendil 5 mg tablete s produljenim oslobađanjem	SE/H/1505/002	HR-H-597365768-02	ASTRAZENECA D.O.O.	HR
Plendil 5 mg tablete s produljenim oslobađanjem	SE/H/1505/002	HR-H-597365768-01	ASTRAZENECA D.O.O.	HR
Plendil 5 mg tablete s produljenim oslobađanjem	SE/H/1505/002	HR-H-597365768-05	ASTRAZENECA D.O.O.	HR
Plendil 5 mg tablete s produljenim oslobađanjem	SE/H/1505/002	HR-H-597365768-06	ASTRAZENECA D.O.O.	HR
Plendil 5 mg tablete s produljenim oslobađanjem	SE/H/1505/002	HR-H-597365768-07	ASTRAZENECA D.O.O.	HR
Plendil 5 mg tablete s produljenim oslobađanjem	SE/H/1505/002	HR-H-597365768-08	ASTRAZENECA D.O.O.	HR
Plendil 5 mg tablete s produljenim oslobađanjem	SE/H/1505/002	HR-H-597365768-09	ASTRAZENECA D.O.O.	HR
Plendil 5 mg tablete s produljenim oslobađanjem	SE/H/1505/002	HR-H-597365768-10	ASTRAZENECA D.O.O.	HR
Plendil 5 mg tablete s produljenim oslobađanjem	SE/H/1505/002	HR-H-597365768-11	ASTRAZENECA D.O.O.	HR
Plendil 10 mg tablete s produljenim oslobađanjem	SE/H/1505/003	HR-H-810293082-01	ASTRAZENECA D.O.O.	HR
Plendil 10 mg tablete s produljenim oslobađanjem	SE/H/1505/003	HR-H-810293082-03	ASTRAZENECA D.O.O.	HR
Plendil 10 mg tablete s produljenim oslobađanjem	SE/H/1505/003	HR-H-810293082-02	ASTRAZENECA D.O.O.	HR
Plendil 10 mg tablete s produljenim oslobađanjem	SE/H/1505/003	HR-H-810293082-04	ASTRAZENECA D.O.O.	HR
Plendil 10 mg tablete s produljenim oslobađanjem	SE/H/1505/003	HR-H-810293082-05	ASTRAZENECA D.O.O.	HR
Plendil 10 mg tablete s produljenim oslobađanjem	SE/H/1505/003	HR-H-810293082-06	ASTRAZENECA D.O.O.	HR
Plendil 10 mg tablete s produljenim oslobađanjem	SE/H/1505/003	HR-H-810293082-07	ASTRAZENECA D.O.O.	HR
Plendil 10 mg tablete s produljenim oslobađanjem	SE/H/1505/003	HR-H-810293082-08	ASTRAZENECA D.O.O.	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
Plendil 10 mg tablete s produljenim oslobađanjem	SE/H/1505/003	HR-H-810293082-09	ASTRAZENECA D.O.O.	HR
Plendil 10 mg tablete s produljenim oslobađanjem	SE/H/1505/003	HR-H-810293082-10	ASTRAZENECA D.O.O.	HR
Plendil 10 mg tablete s produljenim oslobađanjem	SE/H/1505/003	HR-H-810293082-11	ASTRAZENECA D.O.O.	HR
FLODIL L.P. 5 mg, comprimé enrobé à libération prolongée	SE/H/1505/002	3400937143615	ASTRAZENECA S.A.S.	FR
FLODIL L.P. 5 mg, comprimé enrobé à libération prolongée	SE/H/1505/002	3400937143844	ASTRAZENECA S.A.S.	FR
PLENDIL 5 mg Retard, comprimés à libération prolongée	SE/H/1505/002	BE502346	ASTRAZENECA S.A. / N.V.	BE
PLENDIL 5 mg Retard, tabletten met verlengde afgifte	SE/H/1505/002	BE502346	ASTRAZENECA S.A. / N.V.	BE
Plendil 5 mg compresse a rilascio prolungato	SE/H/1505/002	028162067	ASTRAZENECA S.P.A.	IT
Plendil 5 mg compresse a rilascio prolungato	SE/H/1505/002	028162117	ASTRAZENECA S.P.A.	IT
Plendil 5 mg compresse a rilascio prolungato	SE/H/1505/002	028162129	ASTRAZENECA S.P.A.	IT
Plendil 5 mg compresse a rilascio prolungato	SE/H/1505/002	028162079	ASTRAZENECA S.P.A.	IT
Plendil 5 mg compresse a rilascio prolungato	SE/H/1505/002	028162081	ASTRAZENECA S.P.A.	IT
Plendil 5 mg compresse a rilascio prolungato	SE/H/1505/002	028162093	ASTRAZENECA S.P.A.	IT
Plendil 5 mg compresse a rilascio prolungato	SE/H/1505/002	028162105	ASTRAZENECA S.P.A.	IT
Plendil 5 mg compresse a rilascio prolungato	SE/H/1505/002	028162131	ASTRAZENECA S.P.A.	IT
Plendil 5 mg compresse a rilascio prolungato	SE/H/1505/002	028162143	ASTRAZENECA S.P.A.	IT
Plendil 5 mg compresse a rilascio prolungato	SE/H/1505/002	028162156	ASTRAZENECA S.P.A.	IT
Plendil 10 mg compresse a rilascio prolungato	SE/H/1505/003	028162232	ASTRAZENECA S.P.A.	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
Plendil 10 mg compresse a rilascio prolungato	SE/H/1505/003	028162055	ASTRAZENECA S.P.A.	IT
Plendil 10 mg compresse a rilascio prolungato	SE/H/1505/003	028162220	ASTRAZENECA S.P.A.	IT
Plendil 10 mg compresse a rilascio prolungato	SE/H/1505/003	028162194	ASTRAZENECA S.P.A.	IT
Plendil 10 mg compresse a rilascio prolungato	SE/H/1505/003	028162170	ASTRAZENECA S.P.A.	IT
Plendil 10 mg compresse a rilascio prolungato	SE/H/1505/003	028162206	ASTRAZENECA S.P.A.	IT
Plendil 10 mg compresse a rilascio prolungato	SE/H/1505/003	028162168	ASTRAZENECA S.P.A.	IT
Plendil 10 mg compresse a rilascio prolungato	SE/H/1505/003	028162182	ASTRAZENECA S.P.A.	IT
Plendil 10 mg compresse a rilascio prolungato	SE/H/1505/003	028162218	ASTRAZENECA S.P.A.	IT
Plendil 10 mg compresse a rilascio prolungato	SE/H/1505/003	028162244	ASTRAZENECA S.P.A.	IT
Plendil 10 mg, comprimate cu eliberare prelungită	SE/H/1505/003	7360/2015/10	ASTRAZENECA AB	RO
Plendil 10 mg, comprimate cu eliberare prelungită	SE/H/1505/003	7360/2015/04	ASTRAZENECA AB	RO
Plendil 10 mg, comprimate cu eliberare prelungită	SE/H/1505/003	7360/2015/02	ASTRAZENECA AB	RO
Plendil 10 mg, comprimate cu eliberare prelungită	SE/H/1505/003	7360/2015/03	ASTRAZENECA AB	RO
Plendil 10 mg, comprimate cu eliberare prelungită	SE/H/1505/003	7360/2015/12	ASTRAZENECA AB	RO
Plendil 10 mg, comprimate cu eliberare prelungită	SE/H/1505/003	7360/2015/11	ASTRAZENECA AB	RO
Plendil 10 mg, comprimate cu eliberare prelungită	SE/H/1505/003	7360/2015/05	ASTRAZENECA AB	RO
Plendil 10 mg, comprimate cu eliberare prelungită	SE/H/1505/003	7360/2015/08	ASTRAZENECA AB	RO
Plendil 2,5 mg, comprimate cu eliberare prelungită	SE/H/1505/001	7358/2015/03	ASTRAZENECA AB	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
Plendil 10 mg, comprimate cu eliberare prelungită	SE/H/1505/003	7360/2015/09	ASTRAZENECA AB	RO
Plendil 2,5 mg, comprimate cu eliberare prelungită	SE/H/1505/001	7358/2015/08	ASTRAZENECA AB	RO
Plendil 10 mg, comprimate cu eliberare prelungită	SE/H/1505/003	7360/2015/07	ASTRAZENECA AB	RO
Plendil 10 mg, comprimate cu eliberare prelungită	SE/H/1505/003	7360/2015/06	ASTRAZENECA AB	RO
Plendil 2,5 mg, comprimate cu eliberare prelungită	SE/H/1505/001	7358/2015/09	ASTRAZENECA AB	RO
Plendil 2,5 mg, comprimate cu eliberare prelungită	SE/H/1505/001	7358/2015/06	ASTRAZENECA AB	RO
Plendil 2,5 mg, comprimate cu eliberare prelungită	SE/H/1505/001	7358/2015/07	ASTRAZENECA AB	RO
Plendil 5 mg, comprimate cu eliberare prelungită	SE/H/1505/002	7359/2015/10	ASTRAZENECA AB	RO
Plendil 2,5 mg, comprimate cu eliberare prelungită	SE/H/1505/001	7358/2015/04	ASTRAZENECA AB	RO
Plendil 2,5 mg, comprimate cu eliberare prelungită	SE/H/1505/001	7358/2015/05	ASTRAZENECA AB	RO
Plendil 5 mg, comprimate cu eliberare prelungită	SE/H/1505/002	7359/2015/11	ASTRAZENECA AB	RO
Plendil 2,5 mg, comprimate cu eliberare prelungită	SE/H/1505/001	7358/2015/02	ASTRAZENECA AB	RO
PLENDIL 5 mg comprimate cu eliberare prelungită	SE/H/1505/002	7359/2015/05	ASTRAZENECA AB	RO
Plendil 5 mg, comprimate cu eliberare prelungită	SE/H/1505/002	7359/2015/07	ASTRAZENECA AB	RO
Plendil 5 mg, comprimate cu eliberare prelungită	SE/H/1505/002	7359/2015/03	ASTRAZENECA AB	RO
Plendil 5 mg, comprimate cu eliberare prelungită	SE/H/1505/002	7359/2015/06	ASTRAZENECA AB	RO
Plendil 5 mg, comprimate cu eliberare prelungită	SE/H/1505/002	7359/2015/02	ASTRAZENECA AB	RO
PLENDIL 5 mg comprimate cu eliberare prelungită	SE/H/1505/002	7359/2015/04	ASTRAZENECA AB	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
Plendil 5 mg, comprimate cu eliberare prelungită	SE/H/1505/002	7359/2015/09	ASTRAZENECA AB	RO
Plendil 5 mg, comprimate cu eliberare prelungită	SE/H/1505/002	7359/2015/08	ASTRAZENECA AB	RO