



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

6 September 2018  
EMA/609153/2018  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: felodipine

Procedure no.: PSUSA/00001356/201712

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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 retard 2,5 mg - Filmtabletten	SE/H/1505/001	1-20.523	ASTRAZENECA OSTERREICH GMBH	AT
Plendil retard 5 mg - Filmtabletten	SE/H/1505/002	1-18766	ASTRAZENECA OSTERREICH GMBH	AT
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 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 5 mg Retard, tabletten met verlengde afgifte	SE/H/1505/002	BE141251	ASTRAZENECA S.A. / N.V.	BE
PLENDIL 5 mg Retard, comprimés à libération prolongée.	SE/H/1505/002	BE141251	ASTRAZENECA S.A. / N.V.	BE
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
Плендил 5 mg таблетки с удължено освобождаване	SE/H/1505/002	9900022	ASTRAZENECA AB	BG
Plendil 10 mg δισκία παρατεταμένης αποδέσμευσης	SE/H/1505/003	12025	ASTRAZENECA AB	CY
Plendil 2,5 mg δισκία παρατεταμένης αποδέσμευσης	SE/H/1505/001	19573	ASTRAZENECA AB	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
Plendil 5 mg δισκία παρατεταμένης αποδέσμευσης	SE/H/1505/002	12026	ASTRAZENECA AB	CY
PLENDIL ER 10 mg	SE/H/1505/003	83/115/92-C/C	ASTRAZENECA UK LIMITED	CZ
PLENDIL ER 5 mg	SE/H/1505/002	83/115/92-B/C	ASTRAZENECA UK LIMITED	CZ
Modip® 10 mg, Retardtabletten	SE/H/1505/003	11310.00.00	ASTRAZENECA GMBH	DE
Modip® 2,5 mg Retardtabletten	SE/H/1505/001	11310.02.00	ASTRAZENECA GMBH	DE
Modip® 5 mg, Retardtabletten	SE/H/1505/002	11310.01.00	ASTRAZENECA GMBH	DE
Plendil, depottabletter	SE/H/1505/003	13000	ASTRAZENECA A/S	DK
Plendil, depottabletter	SE/H/1505/001	14629	ASTRAZENECA A/S	DK
Plendil, depottabletter	SE/H/1505/002	12999	ASTRAZENECA A/S	DK
Plendil, 10 mg toimeainet prolongeeritult vabastav tablett	SE/H/1505/003	146796	ASTRAZENECA AB	EE
Plendil, 2,5 mg toimeainet prolongeeritult vabastav tablett	SE/H/1505/001	165697	ASTRAZENECA AB	EE
Plendil, 5 mg toimeainet prolongeeritult vabastav tablett	SE/H/1505/002	146696	ASTRAZENECA AB	EE
Plendil 5 mg comprimidos de liberación prolongada	SE/H/1505/002	59.269	ASTRAZENECA FARMACÉUTICA SPAIN, S.A.	ES
Plendil 10 mg depottabletti	SE/H/1505/003	10338	ASTRAZENECA OY	FI
Plendil 2,5 mg depottabletti	SE/H/1505/001	10959	ASTRAZENECA OY	FI
Plendil 5 mg depottabletti	SE/H/1505/002	10337	ASTRAZENECA 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
FLODIL L.P. 5 mg, comprimé enrobé à libération prolongée	SE/H/1505/002	3400933285340	ASTRAZENECA S.A.S.	FR
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 10 mg δισκία παρατεταμένης αποδέσμευσης	SE/H/1505/003	8492 / 06-02-2007	ASTRAZENECA S.A	GR
Plendil®	SE/H/1505/001	8492/6-2-2007	ASTRAZENECA S.A	GR
Plendil®	SE/H/1505/002	8492 / 06-02-2007	ASTRAZENECA S.A	GR
Plendil 5 mg tablete s produljenim oslobađanjem	SE/H/1505/002	HR-H-597365768-03	ASTRAZENECA D.O.O.	HR
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

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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

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Plendil 10 mg tablete s produljenim oslobađanjem	SE/H/1505/003	HR-H-810293082-08	ASTRAZENECA D.O.O.	HR
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
Plendil 2,5 mg retard filmtabletta	SE/H/1505/001	OGYI-T-5098/01	ASTRAZENECA KFT.	HU
Plendil 5 mg retard filmtabletta	SE/H/1505/002	OGYI-T-5098/02	ASTRAZENECA KFT.	HU
Plendil 10mg Prolonged-release, Film-coated Tablets	SE/H/1505/003	970/49/3	ASTRAZENECA UK LIMITED	IE
Plendil 2.5mg prolonged release tablets	SE/H/1505/001	PA 970/49/1	ASTRAZENECA UK LIMITED	IE
Plendil 5mg Prolonged-release, Film-coated Tablets	SE/H/1505/002	970/49/2	ASTRAZENECA UK LIMITED	IE
Plendil 10 mg forðatöflur	SE/H/1505/003	870125	ASTRAZENECA A/S	IS
Plendil 2,5 mg forðatöflur	SE/H/1505/001	910137	ASTRAZENECA A/S	IS
Plendil 5 mg forðatöflur	SE/H/1505/002	870124	ASTRAZENECA A/S	IS
Plendil 10 mg compresse a rilascio prolungato	SE/H/1505/003	028162030	ASTRAZENECA S.P.A.	IT
Plendil 5mg compresse a rilascio prolungato	SE/H/1505/002	028162042	ASTRAZENECA S.P.A.	IT
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

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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
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

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Plendil 10 mg compresse a rilascio prolungato	SE/H/1505/003	028162244	ASTRAZENECA S.P.A.	IT
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	027377034	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 pailginto atpalaidavimo tabletės	SE/H/1505/003	LT/1/96/0438/003	ASTRAZENECA AB	LT
Plendil 2,5 mg pailginto atpalaidavimo tabletės	SE/H/1505/001	LT/1/96/0438/001	ASTRAZENECA AB	LT
Plendil 5 mg pailginto atpalaidavimo tabletės	SE/H/1505/002	LT/1/96/0438/002	ASTRAZENECA AB	LT
Plendil 2,5 mg pailginto atpalaidavimo tabletės	SE/H/1505/001	LT/1/96/0438/010	ASTRAZENECA AB	LT
Plendil 5 mg pailginto atpalaidavimo tabletės	SE/H/1505/002	LT/1/96/0438/012	ASTRAZENECA AB	LT
Plendil 5 mg pailginto atpalaidavimo tabletės	SE/H/1505/002	LT/1/96/0438/020	ASTRAZENECA AB	LT
Plendil 5 mg pailginto atpalaidavimo tabletės	SE/H/1505/002	LT/1/96/0438/018	ASTRAZENECA AB	LT



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Plendil 5 mg pailginto atpalaidavimo tabletės	SE/H/1505/002	LT/1/96/0438/017	ASTRAZENECA AB	LT
Plendil 2,5 mg pailginto atpalaidavimo tabletės	SE/H/1505/001	LT/1/96/0438/006	ASTRAZENECA AB	LT
Plendil 2,5 mg pailginto atpalaidavimo tabletės	SE/H/1505/001	LT/1/96/0438/005	ASTRAZENECA AB	LT
Plendil 2,5 mg pailginto atpalaidavimo tabletės	SE/H/1505/001	LT/1/96/0438/004	ASTRAZENECA AB	LT
Plendil 5 mg pailginto atpalaidavimo tabletės	SE/H/1505/002	LT/1/96/0438/013	ASTRAZENECA AB	LT
Plendil 5 mg pailginto atpalaidavimo tabletės	SE/H/1505/002	LT/1/96/0438/014	ASTRAZENECA AB	LT
Plendil 5 mg pailginto atpalaidavimo tabletės	SE/H/1505/002	LT/1/96/0438/019	ASTRAZENECA AB	LT
Plendil 2,5 mg pailginto atpalaidavimo tabletės	SE/H/1505/001	LT/1/96/0438/011	ASTRAZENECA AB	LT
Plendil 2,5 mg pailginto atpalaidavimo tabletės	SE/H/1505/001	LT/1/96/0438/007	ASTRAZENECA AB	LT
Plendil 2,5 mg pailginto atpalaidavimo tabletės	SE/H/1505/001	LT/1/96/0438/009	ASTRAZENECA AB	LT
Plendil 5 mg pailginto atpalaidavimo tabletės	SE/H/1505/002	LT/1/96/0438/015	ASTRAZENECA AB	LT
Plendil 2,5 mg pailginto atpalaidavimo tabletės	SE/H/1505/001	LT/1/96/0438/008	ASTRAZENECA AB	LT
Plendil 5 mg pailginto atpalaidavimo tabletės	SE/H/1505/002	LT/1/96/0438/016	ASTRAZENECA AB	LT
Plendil 5 mg pailginto atpalaidavimo tabletės	SE/H/1505/002	LT/1/96/0438/021	ASTRAZENECA AB	LT
Plendil 10 mg pailginto atpalaidavimo tabletės	SE/H/1505/003	LT/1/96/0438/022	ASTRAZENECA AB	LT
Plendil 10 mg pailginto atpalaidavimo tabletės	SE/H/1505/003	LT/1/96/0438/025	ASTRAZENECA AB	LT
Plendil 10 mg pailginto atpalaidavimo tabletės	SE/H/1505/003	LT/1/96/0438/024	ASTRAZENECA AB	LT

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Plendil 10 mg pailginto atpalaidavimo tabletės	SE/H/1505/003	LT/1/96/0438/023	ASTRAZENECA AB	LT
Plendil 10 mg pailginto atpalaidavimo tabletės	SE/H/1505/003	LT/1/96/0438/030	ASTRAZENECA AB	LT
Plendil 10 mg pailginto atpalaidavimo tabletės	SE/H/1505/003	LT/1/96/0438/029	ASTRAZENECA AB	LT
Plendil 10 mg pailginto atpalaidavimo tabletės	SE/H/1505/003	LT/1/96/0438/027	ASTRAZENECA AB	LT
Plendil 10 mg pailginto atpalaidavimo tabletės	SE/H/1505/003	LT/1/96/0438/028	ASTRAZENECA AB	LT
Plendil 10 mg pailginto atpalaidavimo tabletės	SE/H/1505/003	LT/1/96/0438/032	ASTRAZENECA AB	LT
Plendil 10 mg pailginto atpalaidavimo tabletės	SE/H/1505/003	LT/1/96/0438/026	ASTRAZENECA AB	LT
Plendil 10 mg pailginto atpalaidavimo tabletės	SE/H/1505/003	LT/1/96/0438/031	ASTRAZENECA AB	LT
PLENDIL 10 mg Retard, comprimés à libération prolongée.	SE/H/1505/003	0173/04118587	ASTRAZENECA S.A. / N.V.	LU
PLENDIL 5 mg Retard, comprimés à libération prolongée	SE/H/1505/002	0173/04118586	ASTRAZENECA S.A. / N.V.	LU
Plendil 10 mg ilgstošās darbības tabletes	SE/H/1505/003	98-0304	ASTRAZENECA AB	LV
Plendil 5mg ilgstošās darbības tabletes	SE/H/1505/002	98-0305	ASTRAZENECA AB	LV
Plendil 5mg Prolonged-release, Film-coated Tablets	SE/H/1505/002	MA 046/00201	ASTRAZENECA AB	MT
Plendil 10, tabletten met verlengde afgifte 10 mg	SE/H/1505/003	RVG 13694	ASTRAZENECA BV	NL
Plendil 2,5, tabletten met verlengde afgifte 2,5 mg	SE/H/1505/001	RVG 15580	ASTRAZENECA BV	NL
Plendil 5, tabletten met verlengde afgifte 5 mg	SE/H/1505/002	RVG 13693	ASTRAZENECA BV	NL

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 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, 10 mg, tabletki o przedłużonym uwalnianiu	SE/H/1505/003	R/3449	ASTRAZENECA AB	PL
Plendil, 5 mg, tabletki o przedłużonym uwalnianiu	SE/H/1505/002	R/3448	ASTRAZENECA AB	PL
Preslow 10 mg comprimidos de libertação prolongada	SE/H/1505/003	2277085	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA	PT
Preslow 5 mg comprimidos de libertação prolongada	SE/H/1505/002	2276988	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA	PT
Preslow 5 mg comprimidos de libertação prolongada	SE/H/1505/002	2276889	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA	PT
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 depottabletter	SE/H/1505/003	10733	ASTRAZENECA AB	SE
PLENDIL 2,5 mg depottabletter	SE/H/1505/001	11442	ASTRAZENECA AB	SE
PLENDIL 5 mg depottabletter	SE/H/1505/002	10732	ASTRAZENECA AB	SE

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Felodipin AstraZeneca 10 mg depottabletter	SE/H/1506/003	18174	ASTRAZENECA AB	SE
Felodipin AstraZeneca 2,5 mg depottabletter	SE/H/1506/001	18172	ASTRAZENECA AB	SE
Felodipin AstraZeneca 5 mg depottabletter	SE/H/1506/002	18173	ASTRAZENECA AB	SE
Plendil 5 mg tablety s predĺženým uvoľňovaním	SE/H/1505/002	83/0545/12-S	ASTRAZENECA AB	SK
Parmid XL 5 mg Prolonged Release Tablets	DE/H/0355/002	PL04416/0458	SANDOZ LTD	UK
Parmid XL 10 mg Prolonged Release Tablets	DE/H/0355/003	PL 4416/0459	SANDOZ LTD	UK
Plendil 10mg	SE/H/1505/003	17901/0155	ASTRAZENECA UK LIMITED	UK
Plendil 2.5mg	SE/H/1505/001	PL 17901/0156	ASTRAZENECA UK LIMITED	UK
Plendil 5mg	SE/H/1505/002	17901/0157	ASTRAZENECA UK LIMITED	UK