



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

9 April 2021  
EMA/210716/2021  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: nifedipine

Procedure no.: PSUSA/00002156/202008

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<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Adalat Oros 20 mg depottabletter	not available	30112	BAYER AB	DK
Adalat Oros 30 mg depottabletter	not available	13973	BAYER AB	DK
Adalat Oros 60 mg depottabletter	not available	13974	BAYER AB	DK
Adalat Oros 30 mg depottabletter	not available	7755	BAYER AB	NO
Adalat Oros 60 mg depottabletter	not available	7756	BAYER AB	NO
Adalat Oros 20 mg depottabletter	not available	98-2503	BAYER AB	NO
Adalat LA 20 mg prolonged-release tablets	not available	PL 00010/0222	BAYER PLC	UK
Adalat LA 30 mg prolonged-release tablets	not available	PL 00010/0174	BAYER PLC	UK
Adalat LA 60 mg prolonged-release tablets	not available	PL 00010/0175	BAYER PLC	UK

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ADALAT CR 30 mg comprimidos de libertação prolongada	not available	8563361	CENTROFARMA LDA	PT
ADALAT CR 60 mg comprimidos de libertação prolongada	not available	8563379	CENTROFARMA LDA	PT
ADALAT CR 30 mg comprimidos de libertação prolongada	not available	8563353	CENTROFARMA LDA	PT
Adalat OROS 30 mg tablete s podaljšanim sproščanjem	not available	H/97/00119/001	BAYER D.O.O	SI
Adalat OROS 60 mg tablete s podaljšanim sproščanjem	not available	H/97/00119/002	BAYER D.O.O	SI
Adalat OROS 60 mg tablete s podaljšanim sproščanjem	not available	H/97/00119/003	BAYER D.O.O	SI
Adalat OROS 30 mg tablete s podaljšanim sproščanjem	not available	H/97/00119/004	BAYER D.O.O	SI
ADALAT CR 30, comprimate cu eliberare modificată, 30 mg	not available	11912/2019/01	BAYER AG	RO
ADALAT 30 mg comprimate cu eliberare prelungită	not available	11912/2019/02	BAYER AG	RO

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NIFEDICOR 20 mg/ml gocce orali, soluzione	not available	024608046	MEDA PHARMA S.P.A.	IT
CHRONADALATE L.P. 30 mg, comprimé osmotique pelliculé à libération prolongée	not available	34009 371 968 3 3	BAYER HEALTHCARE	FR
CHRONADALATE L.P. 30 mg, comprimé osmotique pelliculé à libération prolongée	not available	34009 357 807 6 8	BAYER HEALTHCARE	FR
CHRONADALATE L.P. 30 mg, comprimé osmotique pelliculé à libération prolongée	not available	34009 357 803 0 0	BAYER HEALTHCARE	FR
CHRONADALATE L.P. 30 mg, comprimé osmotique pelliculé à libération prolongée	not available	34009 357 804 7 8	BAYER HEALTHCARE	FR
CHRONADALATE L.P. 30 mg, comprimé osmotique pelliculé à libération prolongée	not available	34009 380 483 9 1	BAYER HEALTHCARE	FR
CHRONADALATE L.P. 30 mg, comprimé osmotique pelliculé à libération prolongée	not available	34009 357 805 3 9	BAYER HEALTHCARE	FR

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CHRONADALATE L.P. 30 mg, comprimé osmotique pelliculé à libération prolongée	not available	34009 571 178 6 3	BAYER HEALTHCARE	FR
CHRONADALATE L.P. 30 mg, comprimé osmotique pelliculé à libération prolongée	not available	34009 571 176 3 4	BAYER HEALTHCARE	FR
CHRONADALATE L.P. 30 mg, comprimé osmotique pelliculé à libération prolongée	not available	34009 380 482 2 3	BAYER HEALTHCARE	FR
CHRONADALATE L.P. 30 mg, comprimé osmotique pelliculé à libération prolongée	not available	34009 571 175 7 3	BAYER HEALTHCARE	FR
Valni 20 Retard (Nifedipine)	not available	PL 11311/0458	TILLOMED LABORATORIES LTD	UK
ADALATE 20 mg L.P., comprimé à libération prolongée	not available	34009 557 492 9 5	BAYER HEALTHCARE	FR
ADALATE 20 mg L.P., comprimé à libération prolongée	not available	34009 327 401 1 6	BAYER HEALTHCARE	FR
ADALATE 20 mg L.P., comprimé à libération prolongée	not available	34009 327 402 8 4	BAYER HEALTHCARE	FR

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ADALATE 20 mg L.P., comprimé à libération prolongée	not available	34009 372 387 4 8	BAYER HEALTHCARE	FR
Adalat CR 20 mg δισκία ελεγχόμενης αποδέσμευσης	not available	39967/09.09.09	BAYER HELLAS SA	GR
Adalat CR 60 mg δισκία ελεγχόμενης αποδέσμευσης	not available	39972/09.09.09	BAYER HELLAS SA	GR
Adalat Crono 30 mg compresse a rilascio modificato	not available	027980059	BAYER SPA	IT
Adalat Crono 30 mg compresse a rilascio modificato	not available	027980010	BAYER SPA	IT
Adalat Crono 20 mg compresse a rilascio modificato	not available	027980034	BAYER SPA	IT
Adalat Crono 20 mg compresse a rilascio modificato	not available	027980046	BAYER SPA	IT
Adalat Crono 60 mg compresse a rilascio modificato	not available	027980022	BAYER SPA	IT
Adalat Crono 60 mg compresse a rilascio modificato	not available	027980061	BAYER SPA	IT

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Adalat Oros 30 mg, comprimidos de liberación prolongada.	not available	59.538	BAYER HISPANIA SL	ES
Adalat® LA 30 mg, Retardtabletten	not available	37545.00.00	BAYER AG	DE
Adalat® LA 60 mg, Retardtabletten	not available	37545.01.00	BAYER AG	DE
Adalat LA 30 mg Prolonged-Release Tablet	not available	MA 639/01301	BAYER LTD	MT
Nife-par 5 mg / ml solución oral	not available	78.233	LABORATORIO REIG JOFRE, S.A.	ES
Nifehexal® 60 uno	not available	28391.01.00	HEXAL AG	DE
AMARKOR "30 mg compresse rivestite con film a rilascio prolungato"	not available	035067014	S.F. GROUP SRL	IT
AMARKOR "60 mg compresse rivestite con film a rilascio prolungato"	not available	035067026	S.F. GROUP SRL	IT
Adalat Retard 20 mg, comprimidos de liberación modificada.	not available	56.920	BAYER HISPANIA SL	ES

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Adalat Oros 20 mg depottabletter	not available	13170	BAYER AB	SE
Adalat Oros 60 mg depottabletter	not available	11806	BAYER AB	SE
Adalat Oros 30 mg depottabletter	not available	11805	BAYER AB	SE
Adalat 5 mg/ 50 ml διάλυμα για έγχυση	not available	39979/9-9-2009	BAYER HELLAS SA	GR
Adalat LA 20 mg Prolonged-Release Tablet	not available	PA 1410/25/5	BAYER LTD	IE
Adalat LA 30 mg Prolonged-Release Tablet	not available	PA 1410/25/6	BAYER LTD	IE
Adalat LA 60mg Prolonged-Release Tablet	not available	PA 1410/25/7	BAYER LTD	IE
Adalat A.P. 20 mg comprimidos de libertação prolongada	not available	4659595	CENTROFARMA LDA	PT
Adalat A.P. 20 mg comprimidos de libertação prolongada	not available	9563304	CENTROFARMA LDA	PT



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Adalat A.P. 20 mg comprimidos de libertação prolongada	not available	9563320	CENTROFARMA LDA	PT
Coracten SR capsules 10 mg	not available	PL 00039/0365	UCB PHARMA LTD (SLOUGH GB)	UK
Coracten XL 30 mg	not available	PL 00039/0506	UCB PHARMA LTD (SLOUGH GB)	UK
Coracten XL 60 mg	not available	PL 00039/0507	UCB PHARMA LTD (SLOUGH GB)	UK
Coracten SR capsules 20mg	not available	PL 00039/0367	UCB PHARMA LTD (SLOUGH GB)	UK
Hypolar* Retard 20	not available	PL 04416/0245	SANDOZ LTD	UK
Hypolar Retard 10mg MR Tablets	not available	PL 04416/0283	SANDOZ LTD	UK
Adalat CR 30 mg δισκία ελεγχόμενης αποδέσμευσης	not available	39969/09.09.09	BAYER HELLAS SA	GR
Nifehexal® 30 uno	not available	28391.00.00	HEXAL AG	DE

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Adalat Oros 60 mg forðatöflur	not available	920178	BAYER AB	IS
Adalat Oros 30 mg forðatöflur	not available	920179	BAYER AB	IS
Adalat Oros 20 mg forðatöflur	not available	980235	BAYER AB	IS
Adalat 5, 5 mg cápsulas moles	not available	8419010	CENTROFARMA LDA	PT
Adalat 5, 5 mg cápsulas moles	not available	4659389	CENTROFARMA LDA	PT
Adalat 10, 10 mg cápsulas moles	not available	4659488	CENTROFARMA LDA	PT
Adalat 5, 5 mg cápsulas moles	not available	8419036	CENTROFARMA LDA	PT
Adalat 10, 10 mg cápsulas moles	not available	8419002	CENTROFARMA LDA	PT
Adalat 10 mg cápsulas blandas	not available	52.661	BAYER HISPANIA SL	ES

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Adalat 5 mg - Infusionsflasche	not available	1-19035	BAYER AUSTRIA GMBH	AT
ADALATE 10 mg, capsule molle	not available	34009 322 348 5 1	BAYER HEALTHCARE	FR
ADALATE 10 mg, capsule molle	not available	34009 322 347 9 0	BAYER HEALTHCARE	FR
Adalat GITS 30 mg retard filmdoublette	not available	OGYI-T-6196/01	BAYER AG	HU
Adalat GITS 30 mg retard filmdoublette	not available	OGYI-T-6196/04	BAYER AG	HU