



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

09 September 2024
EMA/420355/2024
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: doxazosin
Procedure no.: PSUSA/00001169/202312

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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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
Alfadil BPH 4 mg depottabletter	DE/H/0161/001	15514	UPJOHN EESV	SE
Cardular® PP Uro 8 mg, Retardtabletten	DE/H/0161/002	43177.01.00	VIATRIS PHARMA GMBH	DE
DOXAZOSINE VIATRIS L.P. 4 mg, comprimé à libération prolongée	DE/H/0161/001	34009 352 053 3 9	VIATRIS UP	FR
DOXAZOSINE VIATRIS L.P. 4 mg, comprimé à libération prolongée	DE/H/0161/001	34009 352 055 6 8	VIATRIS UP	FR
DOXAZOSINE VIATRIS L.P. 4 mg, comprimé à libération prolongée	DE/H/0161/001	34009 376 256 1 6	VIATRIS UP	FR
DOXAZOSINE VIATRIS L.P. 8 mg, comprimé à libération prolongée	DE/H/0161/002	34009 376 257 8 4	VIATRIS UP	FR
DOXAZOSINE VIATRIS L.P. 8 mg, comprimé à libération prolongée	DE/H/0161/002	34009 352 057 9 7	VIATRIS UP	FR
DOXAZOSINE VIATRIS L.P. 8 mg, comprimé à libération prolongée	DE/H/0161/002	34009 352 056 2 9	VIATRIS UP	FR
Cardular® PP Uro 4 mg, Retardtabletten	DE/H/0161/001	43177.00.00	VIATRIS PHARMA GMBH	DE
Alfadil BPH 8 mg depottabletter	DE/H/0161/002	15515	UPJOHN EESV	SE
Doxazosin 2mg tablets	not available	PL 49565/0005	RUDIPHARM LIMITED	XI
Doxazosin 4mg tablets	not available	PL 49565/0006	RUDIPHARM LIMITED	XI
CARDURA, 4 mg, tabletki	not available	R/3570	UPJOHN EESV	PL
CARDURA, 1 mg, tabletki	not available	R/3568	UPJOHN EESV	PL
CARDURA, 2 mg, tabletki	not available	R/3569	UPJOHN EESV	PL
CARDURA 2mg Tablets	not available	MA1396/00302	VIATRIS HELLAS LTD.	MT
CARDURA 1mg Tablets	not available	MA1396/00301	VIATRIS HELLAS LTD.	MT
Cardura XL 8, tabletten met gereguleerde afgifte 8 mg	not available	RVG 22689	VIATRIS NETHERLANDS B.V.	NL
Cardura XL 4, tabletten met	not available	RVG 22688	VIATRIS NETHERLANDS B.V.	NL

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gereguleerde afgifte 4 mg				
CARDURAN NEO 4 mg comprimidos de liberación modificada	not available	62655	VIATRIS HEALTHCARE LTD	ES
CARDURAN NEO 8 mg comprimidos de liberación modificada.	not available	62.656	VIATRIS HEALTHCARE LTD	ES
CARDURA 2 mg tabletés	not available	LT/1/97/2045/002	UPJOHN EESV	LT
CARDURA 4 mg tabletés	not available	LT/1/97/2045/003	UPJOHN EESV	LT
CARDURA 1 mg tabletés	not available	LT/1/97/2045/001	UPJOHN EESV	LT
Doxazosin Actavis 4 mg Retardtabletten	DK/H/0608/001	1-28371	ACTAVIS GROUP PTC EHF.	AT
Cardura 2 mg tableta	not available	OGYI-T-4980/01	VIATRIS HEALTHCARE LTD	HU
Cardura 4 mg tableta	not available	OGYI-T-4980/02	VIATRIS HEALTHCARE LTD	HU
Carduran Retard, depottabletter	not available	30048	UPJOHN EESV	DK
Carduran Retard, depottabletter	not available	30049	UPJOHN EESV	DK
DEDRALEN 2 mg compresse	not available	027062013	ITALFARMACO S.P.A	IT
DEDRALEN 4 mg compresse	not available	027062025	ITALFARMACO S.P.A	IT
CARDURA 2 mg tabletés	not available	LT/1/97/2045/002	UPJOHN EESV	LT
CARDURA 4 mg tabletés	not available	LT/1/97/2045/003	UPJOHN EESV	LT
CARDURA 1 mg tabletés	not available	LT/1/97/2045/001	UPJOHN EESV	LT
Doxand XL 4mg Prolonged release Tablets	HU/H/0770/001	PL 04416/1584	SANDOZ LTD	XI
Diblocin® PP 4 mg, Retardtabletten	not available	40635.00.00	VIATRIS PHARMA GMBH	DE
Cardura XL 4 mg módosított hatóanyag-leadású filmtabletta	not available	OGYI-T-4980/03	VIATRIS HEALTHCARE LTD	HU
Cardura XL 8 mg módosított hatóanyag-leadású filmtabletta	not available	OGYI-T-4980/06	VIATRIS HEALTHCARE LTD	HU
Cardura XL 4 mg módosított hatóanyag-leadású filmtabletta	not available	OGYI-T-4980/04	VIATRIS HEALTHCARE LTD	HU
Cardura XL 8 mg módosított hatóanyag-leadású filmtabletta	not available	OGYI-T-4980/05	VIATRIS HEALTHCARE LTD	HU
Cardura XL 4 mg, 4 mg	not available	446704	UPJOHN EESV	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
toimeainet prolongeeritult vabastavad tabletid				
Carduran CR 4 mg depottabletter	not available	97-961	UPJOHN EESV	NO
Carduran CR 8 mg depottabletter	not available	97-962	UPJOHN EESV	NO
Carduran Retard 4 mg forðatöflur	not available	980055 (IS)	UPJOHN EESV	IS
Carduran Retard 8 mg forðatöflur	not available	980056 (IS)	UPJOHN EESV	IS
Cardura GITS 4 mg comprimidos de libertação modificada	not available	3080082	UPJOHN EESV	PT
Cardura GITS 4 mg comprimidos de libertação modificada	not available	4594180	UPJOHN EESV	PT
Cardura GITS 4 mg comprimidos de libertação modificada	not available	5466032	UPJOHN EESV	PT
Cardura GITS 4 mg comprimidos de libertação modificada	not available	3080181	UPJOHN EESV	PT
Cardura GITS 4 mg comprimidos de libertação modificada	not available	4594289	UPJOHN EESV	PT
Cardura GITS 8 mg comprimidos de libertação modificada	not available	4594388	UPJOHN EESV	PT
Cardura GITS 8 mg comprimidos de libertação modificada	not available	3080389	UPJOHN EESV	PT
Cardura GITS 8 mg comprimidos de libertação modificada	not available	5466024	UPJOHN EESV	PT
Cardura GITS 8 mg comprimidos de libertação modificada	not available	3080280	UPJOHN EESV	PT
PROGANDOL 2 mg Comprimidos	not available	58.860	ALMIRALL, S.A.	ES
PROGANDOL 4 mg Comprimidos	not available	58.861	ALMIRALL, S.A.	ES
CARDURA®	not available	17364	VIATRIS HELLAS LTD.	CY
CARDURA®	not available	17363	VIATRIS HELLAS LTD.	CY
Cardular® 1 mg Tabletten	not available	9932.00.00	VIATRIS PHARMA GMBH	DE
Cardular® 2 mg Tabletten	not available	9932.01.00	VIATRIS PHARMA GMBH	DE
Cardular® 4 mg Tabletten	not available	9932.02.00	VIATRIS PHARMA GMBH	DE
CARDURA® XL	not available	41099/10/16-06-2011	VIATRIS HELLAS LTD.	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
CARDURA® XL	not available	41101/10/16-06-2011	VIATRIS HELLAS LTD.	GR
Supressin® 2 mg Tabletten	not available	1-18589	MYLAN ÖSTERREICH GMBH	AT
Supressin® 4 mg Tabletten	not available	1-18588	MYLAN ÖSTERREICH GMBH	AT
CARDURA XL 8 mg ilgstošās darbības tabletes	not available	00-0270	UPJOHN EESV	LV
CARDURA XL 4 mg ilgstošās darbības tabletes	not available	00-0269	UPJOHN EESV	LV
PROGANDOL NEO 4 mg Comprimidos de liberación modificada	not available	62.929	ALMIRALL, S.A.	ES
PROGANDOL NEO 8 mg Comprimidos de liberación modificada	not available	62.930	ALMIRALL, S.A.	ES
CARDURA XL 4 mg tablety s prodlouženým uvolňováním	not available	58/537/99-C	UPJOHN EESV	CZ
CARDURA XL 4 mg Prolonged-release tablets	not available	PA 23355/001/001	VIATRIS HEALTHCARE LTD	IE
CARDURA XL 8 mg Prolonged-release tablets	not available	PA 23355/001/002	VIATRIS HEALTHCARE LTD	IE
CARDURA XL 4 mg tablete s podaljšanim sproščanjem	not available	H/02/00344/001	UPJOHN EESV	SI
CARDURA XL 8 mg tablete s podaljšanim sproščanjem	not available	H/02/00344/002	UPJOHN EESV	SI
CARDURA XL 4 mg modifikuoto atpalaidavimo tabletės	not available	LT/1/2000/0809/001	UPJOHN EESV	LT
CARDURA XL 8 mg modifikuoto atpalaidavimo tabletės	not available	LT/1/2000/0809/003	UPJOHN EESV	LT
CARDURA XL 8 mg modifikuoto atpalaidavimo tabletės	not available	LT/1/2000/0809/004	UPJOHN EESV	LT
CARDURA XL 4 mg modifikuoto atpalaidavimo tabletės	not available	LT/1/2000/0809/002	UPJOHN EESV	LT
CARDURA XL 4 mg Prolonged-release tablets	not available	MA1396/00305	VIATRIS HELLAS LTD.	MT
Cardular® PP 8 mg,	DE/H/0132/002	40633.01.00	VIATRIS PHARMA 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
Retardtabletten				
Cardular® PP 4 mg, Retardtabletten	DE/H/0132/001	40633.00.00	VIATRIS PHARMA GMBH	DE
Alfadil 4 mg depottabletter	DE/H/0132/001	14109	UPJOHN EESV	SE
Alfadil 8 mg depottabletter	DE/H/0132/002	14110	UPJOHN EESV	SE
CARDURA 2 mg compresse	not available	026821013	VIATRIS PHARMA S.R.L.	IT
CARDURA 4 mg compresse	not available	026821025	VIATRIS PHARMA S.R.L.	IT
CARDURA 1mg Tablets	not available	PA 23355/003/001	VIATRIS HEALTHCARE LTD	IE
CARDURA 2mg Tablets	not available	PA 23355/003/002	VIATRIS HEALTHCARE LTD	IE
CARDURA®	not available	41152/10/31-05-2011	VIATRIS HELLAS LTD.	GR
CARDURA®	not available	41156/10/16-06-2011	VIATRIS HELLAS LTD.	GR
NORMOTHEN 2 mg compresse	not available	026818017	VIATRIS PHARMA S.R.L.	IT
NORMOTHEN 4 mg compresse	not available	026818029	VIATRIS PHARMA S.R.L.	IT
CARDURA 4 mg tablettes	not available	02-0173	UPJOHN EESV	LV
CARDURA 2mg Tablets	not available	PL 50622/0008	UPJOHN UK LIMITED	XI
CARDURA 1mg Tablets	not available	PL 50622/0007	UPJOHN UK LIMITED	XI
Doxazosin Aurobindo 4 mg tablets	PT/H/1529/003	MA807/09703	AUROBINDO PHARMA (MALTA) LIMITED	MT
Doxazosin Aurobindo 8 mg tablets	PT/H/1529/004	MA807/09704	AUROBINDO PHARMA (MALTA) LIMITED	MT
Doxazosina Aurovitas 1 mg comprimidos	PT/H/1529/001	PT/H/1529/001	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 1 mg comprimidos	PT/H/1529/001	PT/H/1529/001	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 1 mg comprimidos	PT/H/1529/001	PT/H/1529/001	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 1 mg comprimidos	PT/H/1529/001	PT/H/1529/001	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 1 mg comprimidos	PT/H/1529/001	PT/H/1529/001	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 1 mg comprimidos	PT/H/1529/001	PT/H/1529/001	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 1 mg comprimidos	PT/H/1529/001	PT/H/1529/001	GENERIS FARMACÊUTICA, S.A.	PT

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comprimidos			S.A.	
Doxazosina Aurovitas 1 mg comprimidos	PT/H/1529/001	PT/H/1529/001	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 1 mg comprimidos	PT/H/1529/001	PT/H/1529/001	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 1 mg comprimidos	PT/H/1529/001	PT/H/1529/001	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 1 mg comprimidos	PT/H/1529/001	PT/H/1529/001	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 1 mg comprimidos	PT/H/1529/001	PT/H/1529/001	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 1 mg comprimido	PT/H/1529/001	PT/H/1529/001	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 8 mg comprimido	PT/H/1529/004	PT/H/1529/004	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 8 mg Comprimido.	PT/H/1529/004	PT/H/1529/004	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 8 mg comprimidos	PT/H/1529/004	PT/H/1529/004	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 8 mg Comprimido	PT/H/1529/004	PT/H/1529/004	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 8 mg comprimidos	PT/H/1529/004	PT/H/1529/004	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 8 mg comprimidos	PT/H/1529/004	PT/H/1529/004	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 8 mg comprimidos	PT/H/1529/004	PT/H/1529/004	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 8 mg comprimidos	PT/H/1529/004	PT/H/1529/004	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 8 mg comprimidos	PT/H/1529/004	PT/H/1529/004	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 8 mg comprimidos	PT/H/1529/004	PT/H/1529/004	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 8 mg comprimidos	PT/H/1529/004	PT/H/1529/004	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 8 mg comprimidos	PT/H/1529/004	PT/H/1529/004	GENERIS FARMACÊUTICA, S.A.	PT

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comprimidos			S.A.	
Doxazosina Aurovitas 8 mg Comprimido	PT/H/1529/004	PT/H/1529/004	GENERIS FARMACÊUTICA, S.A.	PT
Doxazosina Aurovitas 8 mg comprimidos	PT/H/1529/004	PT/H/1529/004	GENERIS FARMACÊUTICA, S.A.	PT
CARDURA XL, 8 mg, tabletki o zmodyfikowanym uwalnianiu	not available	4315	UPJOHN EESV	PL
CARDURA XL, 4 mg, tabletki o zmodyfikowanym uwalnianiu	not available	4314	UPJOHN EESV	PL
Cardura XL 4 mg comprimate cu eliberare modificată	not available	1245/2008/01	UPJOHN EESV	RO
Cardura XL 4 mg comprimate cu eliberare modificată	not available	1245/2008/02	UPJOHN EESV	RO
CARDURA XL 8mg prolonged release tablets	not available	PL 50622/0010	UPJOHN UK LIMITED	XI
CARDURA XL 4mg prolonged release tablets	not available	PL 50622/0009	UPJOHN UK LIMITED	XI
BENUR 2 mg compresse	not available	029467014	VIATRIS PHARMA S.R.L.	IT
BENUR 4 mg compresse	not available	029467026	VIATRIS PHARMA S.R.L.	IT
Cardura, 2 mg tabletid	not available	196298	UPJOHN EESV	EE
Cardura, 4 mg tabletid	not available	196398	UPJOHN EESV	EE
КАРДУРА 2 mg таблетки	not available	9600208	UPJOHN EESV	BG
КАРДУРА 1 mg таблетки	not available	9600207	UPJOHN EESV	BG
КАРДУРА 4 mg таблетки	not available	9600209	UPJOHN EESV	BG