



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 September 2021
EMA/501908/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: doxazosin

Procedure no.: PSUSA/00001169/202012



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
Cardular® PP Uro 4 mg, Retardtabletten	DE/H/0161/001	43177.00.00	PFIZER OFG GERMANY GMBH	DE
Cardular® PP Uro 8 mg, Retardtabletten	DE/H/0161/002	43177.01.00	PFIZER OFG GERMANY GMBH	DE
ZOXAN LP 8 mg, comprimé à libération prolongée	DE/H/0161/002	34009 352 057 9 7	PFIZER PFE FRANCE	FR
ZOXAN LP 4 mg, comprimé à libération prolongée	DE/H/0161/001	34009 352 053 3 9	PFIZER PFE FRANCE	FR
ZOXAN LP 8 mg, comprimé à libération prolongée	DE/H/0161/002	34009 352 056 2 9	PFIZER PFE FRANCE	FR
ZOXAN LP 8 mg, comprimé à libération prolongée	DE/H/0161/002	34009 376 257 8 4	PFIZER PFE FRANCE	FR
ZOXAN LP 4 mg, comprimé à libération prolongée	DE/H/0161/001	34009 376 256 1 6	PFIZER PFE FRANCE	FR
ZOXAN LP 4 mg, comprimé à libération prolongée	DE/H/0161/001	34009 352 055 6 8	PFIZER PFE FRANCE	FR
Alfadil BPH 4 mg depottabletter	DE/H/0161/001	15514	PFIZER AB	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
Alfadil BPH 8 mg depottabletten	DE/H/0161/002	15515	PFIZER AB	SE
NORMOTHEN 2 mg compresse	not available	026818017	PFIZER ESTABLISHED MEDICINE ITALY S.R.L.	IT
NORMOTHEN 4 mg compresse	not available	026818029	PFIZER ESTABLISHED MEDICINE ITALY S.R.L.	IT
Carduran Retard, depottabletten	not available	30049	PFIZER APS	DK
Carduran Retard, depottabletten	not available	30048	PFIZER APS	DK
CARDURA 4 mg compresse	not available	026821025	PFIZER ITALIA S.R.L.	IT
CARDURA 2 mg compresse	not available	026821013	PFIZER ITALIA S.R.L.	IT
CARDURA, 1 mg, tabletki	not available	R/3568	UPJOHN EESV	PL
CARDURA, 2 mg, tabletki	not available	R/3569	UPJOHN EESV	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
CARDURA, 4 mg, tabletki	not available	R/3570	UPJOHN EESV	PL
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®	not available	41152/10/31-05-2011	UPJOHN HELLAS L.T.D.	GR
CARDURA®	not available	41156/10/16-06-2011	UPJOHN HELLAS L.T.D.	GR
BENUR 4 mg compresse	not available	029467026	PFIZER ITALIA S.R.L.	IT
BENUR 2 mg compresse	not available	029467014	PFIZER ITALIA S.R.L.	IT
КАРДУРА 2 mg таблетки	not available	9600208	UPJOHN EESV	BG
КАРДУРА 4 mg таблетки	not available	9600209	UPJOHN EESV	BG

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
КАРДУРА 1 mg таблетки	not available	9600207	UPJOHN EESV	BG
Cardura XL 4, tabletten met gereguleerde afgifte 4 mg	not available	RVG 22688	PFIZER B.V.	NL
Cardura XL 8, tabletten met gereguleerde afgifte 8 mg	not available	RVG 22689	PFIZER B.V.	NL
CARDURA XL 4 mg ilgstošās darbības tabletes	not available	00-0269	UPJOHN EESV	LV
CARDURA XL 8 mg ilgstošās darbības tabletes	not available	00-0270	UPJOHN EESV	LV
Doxand XL 4mg Prolonged release Tablets	ES/H/0649/001	PL 04416/1584	SANDOZ LTD	XI
CARDURA 4 mg tabletes	not available	02-0173	UPJOHN EESV	LV
Cardura XL 8 mg módosított hatóanyag-leadású filmtabletta	not available	OGYI-T-4980/06	UPJOHN EESV	HU
Cardura XL 4 mg módosított hatóanyag-leadású filmtabletta	not available	OGYI-T-4980/03	UPJOHN EESV	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
Cardura XL 4 mg módosított hatóanyag- leadású filmtabletta	not available	OGYI-T-4980/04	UPJOHN EESV	HU
Cardura XL 8 mg módosított hatóanyag- leadású filmtabletta	not available	OGYI-T-4980/05	UPJOHN EESV	HU
CARDURA XL, 8 mg, tabletki o zmodyfikowanym uwalnieniu	not available	4315	UPJOHN EESV	PL
CARDURA XL, 4 mg, tabletki o zmodyfikowanym uwalnieniu	not available	4314	UPJOHN EESV	PL
Cardura GITS 8 mg comprimidos de libertação modificada	not available	4594388	LABORATÓRIOS PFIZER, LDA.	PT
Cardura GITS 8 mg comprimidos de libertação modificada	not available	3080389	LABORATÓRIOS PFIZER, LDA.	PT
Cardura GITS 8 mg comprimidos de libertação modificada	not available	5466024	LABORATÓRIOS PFIZER, LDA.	PT
Cardura GITS 8 mg comprimidos de libertação modificada	not available	3080280	LABORATÓRIOS PFIZER, LDA.	PT

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 GITS 4 mg comprimidos de libertação modificada	not available	4594289	LABORATÓRIOS PFIZER, LDA.	PT
Cardura GITS 4 mg comprimidos de libertação modificada	not available	5466032	LABORATÓRIOS PFIZER, LDA.	PT
Cardura GITS 4 mg comprimidos de libertação modificada	not available	3080181	LABORATÓRIOS PFIZER, LDA.	PT
Cardura GITS 4 mg comprimidos de libertação modificada	not available	3080082	LABORATÓRIOS PFIZER, LDA.	PT
Cardura GITS 4 mg comprimidos de libertação modificada	not available	4594180	LABORATÓRIOS PFIZER, LDA.	PT
Cardura, 2 mg tabletid	not available	196298	UPJOHN EESV	EE
Cardura, 4 mg tabletid	not available	196398	UPJOHN EESV	EE
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

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 4 mg tabletės	not available	LT/1/97/2045/003	UPJOHN EESV	LT
CARDURA 1 mg tabletės	not available	LT/1/97/2045/001	UPJOHN EESV	LT
CARDURA 2 mg tabletės	not available	LT/1/97/2045/002	UPJOHN EESV	LT
CARDURA XL 4 mg tablety s prodlouženým uvolňováním	not available	58/537/99-C	UPJOHN EESV	CZ
Supressin® 2 mg Tabletten	not available	1-18589	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Supressin® 4 mg Tabletten	not available	1-18588	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Cardular® 4 mg Tabletten	not available	9932.02.00	PFIZER OFG GERMANY GMBH	DE
Cardular® 1 mg Tabletten	not available	9932.00.00	PFIZER OFG GERMANY GMBH	DE
Cardular® 2 mg Tabletten	not available	9932.01.00	PFIZER OFG GERMANY 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
Carduran Retard 8 mg forðatöflur	not available	980056	UPJOHN EESV	IS
Carduran Retard 4 mg forðatöflur	not available	980055	UPJOHN EESV	IS
Diblocin® PP 4 mg, Retardtabletten	not available	40635.00.00	PFIZER OFG GERMANY GMBH	DE
CARDURA XL 4 mg modifikuoto atpalaidavimo tabletės	not available	LT/1/2000/0809/001	UPJOHN EESV	LT
CARDURA XL 4 mg modifikuoto atpalaidavimo tabletės	not available	LT/1/2000/0809/002	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 8 mg Prolonged-release tablets	not available	PA 822/4/2	PFIZER HEALTHCARE IRELAND	IE
CARDURA XL 4 mg Prolonged-release tablets	not available	PA 822/4/1	PFIZER HEALTHCARE IRELAND	IE

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
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®	not available	17363	UPJOHN HELLAS L.T.D.	CY
CARDURA®	not available	17364	UPJOHN HELLAS L.T.D.	CY
CARDURA® XL	not available	41101/10/16-06-2011	UPJOHN HELLAS L.T.D.	GR
CARDURA® XL	not available	41099/10/16-06-2011	UPJOHN HELLAS L.T.D.	GR
Cardular® PP 4 mg, Retardtabletten	DE/H/0132/001	40633.00.00	PFIZER OFG GERMANY GMBH	DE
Cardular® PP 8 mg, Retardtabletten	DE/H/0132/002	40633.01.00	PFIZER OFG GERMANY GMBH	DE
Alfadil 8 mg depottabletter	DE/H/0132/002	14110	PFIZER AB	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
Alfadil 4 mg depottabletter	DE/H/0132/001	14109	PFIZER AB	SE
Carduran CR 8 mg depottabletter	not available	97-962	PFIZER AS	NO
Carduran CR 4 mg depottabletter	not available	97-961	PFIZER AS	NO
Diblocin® PP 4 mg, Retardtabletten	not available	40635.00.00	PFIZER OFG GERMANY GMBH	DE
CARDURA 2mg Tablets	not available	PA 0822/192/002	PFIZER HEALTHCARE IRELAND	IE
CARDURA 1mg Tablets	not available	PA 0822/192/001	PFIZER HEALTHCARE IRELAND	IE
Cardura 2 mg tabletta	not available	OGYI-T-4980/01	UPJOHN EESV	HU
Cardura 4 mg tabletta	not available	OGYI-T-4980/02	UPJOHN EESV	HU
CARDURA 1mg Tablets	not available	MA1396/00301	UPJOHN HELLAS L.T.D.	MT

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 2mg Tablets	not available	MA1396/00302	UPJOHN HELLAS L.T.D.	MT
CARDURAN NEO 8 mg comprimidos de liberación modificada	not available	62.656	PFIZER, S.L.	ES
CARDURAN NEO 4 mg comprimidos de liberación modificada	not available	62.655	PFIZER, S.L.	ES
CARDURA XL 8 mg tablete s podaljšanim sproščanjem	not available	H/02/00344/002	UPJOHN EESV	SI
CARDURA XL 4 mg tablete s podaljšanim sproščanjem	not available	H/02/00344/001	UPJOHN EESV	SI
Cardura XL 4 mg, 4 mg toimeainet prolongeeritult vabastavad tabletid	not available	446704	UPJOHN EESV	EE
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 8 mg Prolonged-release tablets	not available	PA 822/4/2	PFIZER HEALTHCARE IRELAND	IE

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 4 mg Prolonged-release tablets	not available	PA 822/4/1	PFIZER HEALTHCARE IRELAND	IE
Doxazosin Actavis 4 mg Retardtabletten	DK/H/0608/001	1-28371	ACTAVIS GROUP PTC EHF.	AT
PROGANDOL 2 mg Comprimidos	not available	58.860	ALMIRALL, S.A.	ES
PROGANDOL 4 mg Comprimidos	not available	58.861	ALMIRALL, S.A.	ES
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