



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 September 2016
EMA/690449/2016
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: doxazosin

Procedure no.: PSUSA/00001169/201512

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Send a question via our website www.ema.europa.eu/contact

An agency of the European Union



| Product full name | 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 |
| DEDRALEN 2 mg compresse | not available | 027062013 | ITALFARMACO S.P.A | IT |
| DEDRALEN 4 mg compresse | not available | 027062025 | ITALFARMACO S.P.A | IT |
| 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 |

| Product full name | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|------------------------------|-------------------------------|--|--|
| PROGANDOL 4 mg Comprimidos | not available | 58.861 | ALMIRALL, S.A. | ES |
| CARDURA XL 8 mg tablete s podaljšanim sproščanjem | not available | H/02/00344/002 | PFIZER LUXEMBOURG SARL | SI |
| CARDURA XL 4 mg tablete s podaljšanim sproščanjem | not available | H/02/00344/001 | PFIZER LUXEMBOURG SARL | SI |
| CARDURA™ XL 8mg | not available | PL 00057/0418 | PFIZER LIMITED | UK |
| CARDURA™ XL 4mg | not available | PL 00057/0417 | PFIZER LIMITED | UK |
| Supressin® 2 mg Tabletten | not available | 1-18589 | PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H. | AT |

| Product full name | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|--|---|----------------------------------|---|---|
| CARDURA™ 2mg | not available | MA505/02902 | PFIZER HELLAS, A.E. | MT |
| CARDURAXL 8 mg Prolonged-release tablets | not available | PA 0822/004/002 | PFIZER HEALTHCARE IRELAND | IE |
| CARDURA XL 4 mg Prolonged-release tablets | not available | PA 0822/004/001 | PFIZER HEALTHCARE IRELAND | IE |
| CARDURA™ 1mg | not available | PL 00057/0276 | PFIZER LIMITED | UK |
| Supressin® 4 mg Tabletten | not available | 1-18588 | PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H. | AT |
| CARDURA 2mg Tablets | not available | PA 0019/043/002 | PFIZER LIMITED | IE |

| Product full name | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|--|------------------------------|-------------------------------|------------------------------------|--|
| CARDURA 1mg Tablets | not available | PA 0019/043/001 | PFIZER LIMITED | IE |
| CARDURA™ 2mg | not available | PL 00057/0277 | PFIZER LIMITED | UK |
| CARDURA™ 1mg | not available | MA505/02901 | PFIZER HELLAS, A.E. | MT |
| CARDURA XL 4 mg modifikuoto atpalaidavimo tabletės | not available | LT/1/2000/0809/001 | PFIZER EUROPE MA EEIG | LT |
| КАРДУРА 2 мг таблетки | not available | 9600208 | PFIZER EUROPE MA EEIG | BG |
| Carduran CR 8 mg depottabletter | not available | 97-962 | PFIZER AS | NO |

| Product full name | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---------------------------------|------------------------------|-------------------------------|------------------------------------|--|
| Cardura, 2 mg tabletid | not available | 196298 | PFIZER EUROPE MA EEIG | EE |
| Carduran Retard, depottabletter | not available | 30049 | PFIZER APS | DK |
| КАРДУРА 4 мг таблетки | not available | 9600209 | PFIZER EUROPE MA EEIG | BG |
| CARDURA, 1 mg, tabletki | not available | R/3568 | PFIZER EUROPE MA EEIG | PL |
| Carduran CR 4 mg depottabletter | not available | 97-961 | PFIZER AS | NO |
| CARDURA, 2 mg, tabletki | not available | R/3569 | PFIZER EUROPE MA EEIG | PL |

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|----------------------------------|------------------------------|-------------------------------|------------------------------------|--|
| CARDURA, 4 mg, tabletki | not available | R/3570 | PFIZER EUROPE MA EEIG | PL |
| NORMOTHEN 2 mg compresse | not available | 026818017 | PFIZER ITALIA S.R.L. | IT |
| NORMOTHEN 4 mg compresse | not available | 026818029 | PFIZER ITALIA S.R.L. | IT |
| CARDURA 4 mg tabletės | not available | LT/1/97/2045/003 | PFIZER EUROPE MA EEIG | LT |
| Cardura, 4 mg tabletid | not available | 196398 | PFIZER EUROPE MA EEIG | EE |
| Carduran Retard 8 mg forðatöflur | not available | 980056 (IS) | PFIZER APS | IS |

| Product full name | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|----------------------------------|---------------------------------------|---|
| CARDURA XL 4 mg modifikuoto atpalaidavimo tabletės | not available | LT/1/2000/0809/002 | PFIZER EUROPE MA EEIG | LT |
| CARDURA 1 mg tabletės | not available | LT/1/97/2045/001 | PFIZER EUROPE MA EEIG | LT |
| Cardura 2 mg tabletta | not available | OGYI-T-4980/01 | PFIZER KFT. | HU |
| CARDURA 4 mg compresse | not available | 026821025 | PFIZER ITALIA S.R.L. | IT |
| CARDURA XL 8 mg modifikuoto atpalaidavimo tabletės | not available | LT/1/2000/0809/003 | PFIZER EUROPE MA EEIG | LT |
| CARDURA 2 mg tabletės | not available | LT/1/97/2045/002 | PFIZER EUROPE MA EEIG | LT |

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|---|------------------------------|-------------------------------|------------------------------------|--|
| Cardura 4 mg tableta | not available | OGYI-T-4980/02 | PFIZER KFT. | HU |
| 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 |
| Alfadil 8 mg depottabletter | DE/H/0132/002 | 14110 | PFIZER AB | SE |
| CARDURA XL 4 mg ilgstošās darbības tabletes | not available | 00-0269 | PFIZER LIMITED | LV |

| Product full name | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|--|------------------------------|-------------------------------|------------------------------------|--|
| CARDURA XL 8 mg ilgstošās darbības tabletes | not available | 00-0270 | PFIZER LIMITED | LV |
| Alfadil 4 mg depottabletter | DE/H/0132/001 | 14109 | PFIZER AB | SE |
| CARDURA 2 mg compresse | not available | 026821013 | PFIZER ITALIA S.R.L. | IT |
| CARDURA® XL | not available | 41101/10/16-06-2011 | PFIZER HELLAS, A.E. | GR |
| CARDURA XL, 8 mg, tabletki o zmodyfikowanym uwalnieniu | not available | 4315 | PFIZER EUROPE MA EEIG | PL |

| Product full name | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|------------------------------|-------------------------------|------------------------------------|--|
| CARDURA™ XL 4mg | not available | AA505/05401 | PFIZER HELLAS, A.E. | MT |
| Carduran Retard, depottabletter | not available | 30048 | PFIZER APS | DK |
| CARDURA XL 4 mg | not available | 58/0066/00-S | PFIZER EUROPE MA EEIG | SK |
| CARDURA | not available | 41152/10/31-05-2011 | PFIZER HELLAS, A.E. | GR |
| Cardura XL 4 mg, comprimate cu eliberare modificată | not available | 1245/2008/01 | PFIZER EUROPE MA EEIG | RO |

| Product full name | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|------------------------------|-------------------------------|------------------------------------|--|
| CARDURA XL, 4 mg, tabletki o zmodyfikowanym uwalnianiu | not available | 4314 | PFIZER EUROPE MA EEIG | PL |
| CARDURAN NEO 8 mg comprimidos de liberación modificada | not available | 62.656 | PFIZER, S.L. | ES |
| CARDURA® | not available | 17363 | PFIZER HELLAS, A.E. | CY |
| Cardura XL 8 mg módosított hatóanyag-leadású filmtabletta | not available | OGYI-T-4980/06 | PFIZER KFT. | HU |
| Cardura URO 4 mg módosított hatóanyagleadású filmtabletta | not available | OGYI-T-4980/07 | PFIZER KFT. | HU |
| CARDURA | not available | 41156/10/10/16-06-2011 | PFIZER HELLAS, A.E. | GR |

| Product full name | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|--|------------------------------|-------------------------------|------------------------------------|--|
| Cardura XL 4 mg, comprimate cu eliberare modificată | not available | 1245/2008/02 | PFIZER EUROPE MA EEIG | RO |
| Cardura XL 4 mg módosított hatóanyag-leadású filmtabletta | not available | OGYI-T-4980/03 | PFIZER KFT. | HU |
| CARDURA® XL | not available | 41099/10/16-06-2011 | PFIZER HELLAS, A.E. | GR |
| Cardura XL 4 mg, 4 mg toimeainet prolongeeritult vabastavad tabletid | not available | 446704 | PFIZER EUROPE MA EEIG | EE |
| CARDURA | not available | 17364 | PFIZER HELLAS, A.E. | CY |
| Cardura URO 8 mg módosított hatóanyagleadású filmtabletta | not available | OGYI-T-4980/10 | PFIZER KFT. | HU |

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|---|------------------------------|-------------------------------|------------------------------------|--|
| Cardura XL 4 mg módosított hatóanyag-leadású filmtabletta | not available | OGYI-T-4980/04 | PFIZER KFT. | HU |
| CARDURA 4 mg tabletes | not available | 02-0173 | PFIZER LIMITED | LV |
| CARDURA XL 4 mg tablety s prodlouženým uvolňováním | not available | 58/537/99-C | PFIZER, SPOL. S R.O. | CZ |
| CARDURA XL 8 mg | not available | 58/0067/00-S | PFIZER EUROPE MA EEIG | SK |
| Cardura XL 8 mg módosított hatóanyag-leadású filmtabletta | not available | OGYI-T-4980/05 | PFIZER KFT. | HU |
| Cardura URO 8 mg módosított hatóanyagleadású filmtabletta | not available | OGYI-T-4980/09 | PFIZER KFT. | HU |

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|---|------------------------------|-------------------------------|------------------------------------|--|
| Cardura URO 4 mg módosított hatóanyagleadású filmtabletta | not available | OGYI-T-4980/08 | PFIZER KFT. | HU |
| Carduran Retard 4 mg forðatöflur | not available | 980055 (IS) | PFIZER APS | IS |
| CARDURAN NEO 4 mg comprimidos de liberación modificada | not available | 62.655 | PFIZER, S.L. | ES |
| Cardular® PP 4 mg, Retardtabletten | DE/H/0132/001 | 40633.00.00 | PFIZER PHARMA GMBH | DE |
| Cardular® PP Uro 4 mg, Retardtabletten | DE/H/0161/001 | 43177.00.00 | PFIZER PHARMA GMBH | DE |

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|--|------------------------------|-------------------------------|------------------------------------|--|
| Cardular® PP Uro 8 mg, Retardtabletten | DE/H/0161/002 | 43177.01.00 | PFIZER PHARMA GMBH | DE |
| Diblocin® PP 4 mg, Retardtabletten | not available | 40635.00.00 | PFIZER PHARMA GMBH | DE |
| Cardular® PP 8 mg, Retardtabletten | DE/H/0132/002 | 40633.01.00 | PFIZER PHARMA GMBH | DE |
| 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 |

| Product full name | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|--------------------------|------------------------------|-------------------------------|------------------------------------|--|
| Cardular® 1 mg Tabletten | not available | 9932.00.00 | PFIZER PHARMA GMBH | DE |
| Cardular® 4 mg Tabletten | not available | 9932.02.00 | PFIZER PHARMA GMBH | DE |
| КАРДУРА 1 mg таблетки | not available | 9600207 | PFIZER EUROPE MA EEIG | BG |
| Cardular® 2 mg Tabletten | not available | 9932.01.00 | PFIZER PHARMA GMBH | DE |

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|----------------------------------|------------------------------------|----------------------------------|---------------------------------------|---|
| Alfadil BPH, 4 mg depottabletter | DE/H/0161/001 | 15514 | PFIZER AB | SE |
| Alfadil BPH, 8 mg depottabletter | DE/H/0161/002 | 15515 | PFIZER AB | SE |
| Doxazosin 2mg tablets | not available | PL 21880/0035 | MEDREICH PLC | UK |
| Doxazosin 4mg tablets | not available | PL 21880/0036 | MEDREICH PLC | UK |

| Product full name | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|--|------------------------------|-------------------------------|------------------------------------|--|
| ZOXAN LP | DE/H/0161/001-002 | NL 24 552 | PFIZER HOLDING FRANCE (S.C.A.) | FR |
| ZOXAN LP 4 mg, comprimé à libération prolongée | DE/H/0161/001-002 | NL 24 553 | PFIZER HOLDING FRANCE (S.C.A.) | FR |
| Cardura GITS 4mg | not available | 94/H/46/001 | LABORATÓRIOS PFIZER, LDA. | PT |
| Cardura GITS 8 mg | not available | 94/H/46/002 | LABORATÓRIOS PFIZER, LDA. | PT |