



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 September 2017
EMA/652910/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: Moxonidine

Procedure no.: PSUSA/00002095/201701



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
Cynt 0,2, potahované tablety	not available	58/385/96-A/C	MYLAN HEALTHCARE GMBH	CZ
Cynt 0,4, potahované tablety	not available	58/385/96-C/C	MYLAN HEALTHCARE GMBH	CZ
Cynt 0,3, potahované tablety	not available	58/385/96-B/C	MYLAN HEALTHCARE GMBH	CZ
Moxon 0,2 mg comprimido revestido	not available	4895785	BGP PRODUCTS UNIPESOAL, LDA.	PT
Moxon 0,2 mg comprimido revestido	not available	3497682	BGP PRODUCTS UNIPESOAL, LDA.	PT
Moxon 0,2 mg comprimido revestido	not available	3497583	BGP PRODUCTS UNIPESOAL, LDA.	PT
Moxon 0,4 mg comprimido revestido	not available	3498284	BGP PRODUCTS UNIPESOAL, LDA.	PT
Moxon 0,4 mg comprimido revestido	not available	5800388	BGP PRODUCTS UNIPESOAL, LDA.	PT
Moxon 0,4 mg comprimido revestido	not available	3497989	BGP PRODUCTS UNIPESOAL, LDA.	PT
Moxon 0,3 mg comprimido revestido	not available	3498482	BGP PRODUCTS UNIPESOAL, LDA.	PT
Moxon 0,3 mg comprimido revestido	not available	3498383	BGP PRODUCTS UNIPESOAL, LDA.	PT
MoxonidinHEXAL 0,3 mg plévele dengtos tabletês	/	LT/1/04/3092/009	HEXAL AG	LT
MoxonidinHEXAL 0,3 mg plévele dengtos tabletês	/	LT/1/04/3092/010	HEXAL AG	LT
MoxonidinHEXAL 0,3 mg plévele dengtos tabletês	/	LT/1/04/3092/013	HEXAL AG	LT
MoxonidinHEXAL 0,3 mg plévele dengtos tabletês	/	LT/1/04/3092/014	HEXAL AG	LT

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MoxonidinHEXAL 0,3 mg plévele dengtos tabletès	/	LT/1/04/3092/016	HEXAL AG	LT
MoxonidinHEXAL 0,3 mg plévele dengtos tabletès	/	LT/1/04/3092/015	HEXAL AG	LT
MoxonidinHEXAL 0,3 mg plévele dengtos tabletès	/	LT/1/04/3092/011	HEXAL AG	LT
MoxonidinHEXAL 0,3 mg plévele dengtos tabletès	/	LT/1/04/3092/012	HEXAL AG	LT
Physiotens 0,2 mg comprimate filmate	not available	5991/2013/01	MYLAN HEALTHCARE GMBH	RO
Physiotens 0,2 mg comprimate filmate	not available	5991/2013/02	MYLAN HEALTHCARE GMBH	RO
Physiotens 0,2 mg comprimate filmate	not available	5991/2013/03	MYLAN HEALTHCARE GMBH	RO
Physiotens 0,4 mg comprimate filmate	not available	5992/2013/02	MYLAN HEALTHCARE GMBH	RO
Physiotens 0,4 mg comprimate filmate	not available	5992/2013/03	MYLAN HEALTHCARE GMBH	RO
Physiotens 0,4 mg comprimate filmate	not available	5992/2013/01	MYLAN HEALTHCARE GMBH	RO
MOXON 0,2 mg comprimés pelliculés	not available	BE168822	MYLAN EPD SPRL	BE
MOXON 0,3 mg comprimés pelliculés	not available	BE199613	MYLAN EPD SPRL	BE
MOXON 0,4 mg comprimés pelliculés	not available	BE199622	MYLAN EPD SPRL	BE
MOXON 0,2 mg comprimés pelliculés	not available	2005098212	MYLAN EPD SPRL	LU

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
MOXON 0,3 mg comprimés pelliculés	not available	2005098213	MYLAN EPD SPRL	LU
MOXON 0,4 mg comprimés pelliculés	not available	2005098214	MYLAN EPD SPRL	LU
Физиотенс 0,2 mg филмирани таблетки	not available	9900124	MYLAN HEALTHCARE GMBH	BG
Физиотенс 0,4 mg филмирани таблетки	not available	9900126	MYLAN HEALTHCARE GMBH	BG
Physiotens® 0,2 mg, Filmtabletten	not available	9958.00.00	MYLAN HEALTHCARE GMBH	DE
Physiotens® 0,3 mg, Filmtabletten	not available	9958.01.00	MYLAN HEALTHCARE GMBH	DE
Physiotens® 0,4 mg, Filmtabletten	not available	9958.02.00	MYLAN HEALTHCARE GMBH	DE
Physiotens 0,2 mg, õhukese polümeerikattega tabletid	not available	394902	MYLAN HEALTHCARE GMBH	EE
FISIOTENS ® 0,3mg, επικαλυμμένα με λεπτό υμένιο δισκία.	not available	45593/15-9-2009 (26-1- 2010)	BGP PRODUCTS LTD (GREECE)	GR
FISIOTENS ® 0,4mg, επικαλυμμένα με λεπτό υμένιο δισκία.	not available	45594/15-9-2009 (26-1- 2010)	BGP PRODUCTS LTD (GREECE)	GR
FISIOTENS ® 0,2mg, επικαλυμμένα με λεπτό υμένιο δισκία.	not available	45589/15-9-2009 (26-1- 2010)	BGP PRODUCTS LTD (GREECE)	GR
CYNT ® 0,4mg, επικαλυμμένα με λεπτό υμένιο δισκία	not available	42527/10/21-06-2011	BGP PRODUCTS LTD (GREECE)	GR
CYNT® 0,2mg, επικαλυμμένα με λεπτό υμένιο δισκία	not available	42523/10/21-06-2011	BGP PRODUCTS LTD (GREECE)	GR

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Moxon 0,2 mg comprimidos recubiertos con película	not available	61.156	BGP PRODUCTS OPERATIONS SL	ES
Moxon 0,3 mg comprimidos recubiertos con película	not available	61.157	BGP PRODUCTS OPERATIONS SL	ES
Moxon 0,4 mg comprimidos recubiertos con película	not available	61.158	BGP PRODUCTS OPERATIONS SL	ES
CYNT® 0,3mg, επικαλυμμένα με λεπτό υμένιο δισκία	not available	42524/10/21-06-2011	BGP PRODUCTS LTD (GREECE)	GR
PHYSIOTENS 0,2 mg, comprimé pelliculé	not available	337 782-8	MYLAN MEDICAL SAS	FR
PHYSIOTENS 0,2 mg, comprimé pelliculé	not available	337 783-4	MYLAN MEDICAL SAS	FR
PHYSIOTENS 0,2 mg, comprimé pelliculé	not available	371 485-2	MYLAN MEDICAL SAS	FR
PHYSIOTENS 0,2 mg, comprimé pelliculé	not available	337 784-0	MYLAN MEDICAL SAS	FR
PHYSIOTENS 0,2 mg, comprimé pelliculé	not available	558 526-4	MYLAN MEDICAL SAS	FR
PHYSIOTENS 0,2 mg, comprimé pelliculé	not available	338 313-1	MYLAN MEDICAL SAS	FR
PHYSIOTENS 0,3 mg, comprimé pelliculé	not available	337 785-7	MYLAN MEDICAL SAS	FR
PHYSIOTENS 0,3 mg, comprimé pelliculé	not available	337 786-3	MYLAN MEDICAL SAS	FR
PHYSIOTENS 0,3 mg, comprimé pelliculé	not available	337 788-6	MYLAN MEDICAL SAS	FR
PHYSIOTENS 0,3 mg, comprimé pelliculé	not available	558 527-0	MYLAN MEDICAL SAS	FR

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
PHYSIOTENS 0,3 mg, comprimé pelliculé	not available	338 484-0	MYLAN MEDICAL SAS	FR
PHYSIOTENS 0,4 mg, comprimé pelliculé	not available	337 789-2	MYLAN MEDICAL SAS	FR
PHYSIOTENS 0,4 mg, comprimé pelliculé	not available	337 790-0	MYLAN MEDICAL SAS	FR
PHYSIOTENS 0,4 mg, comprimé pelliculé	not available	371 486-9	MYLAN MEDICAL SAS	FR
PHYSIOTENS 0,4 mg, comprimé pelliculé	not available	337 791-7	MYLAN MEDICAL SAS	FR
PHYSIOTENS 0,4 mg, comprimé pelliculé	not available	558 528-7	MYLAN MEDICAL SAS	FR
PHYSIOTENS 0,4 mg, comprimé pelliculé	not available	338 483-4	MYLAN MEDICAL SAS	FR
Cynt 0,2 mg filmom obložene tablete	not available	UP/I-530-09/11-01/316	MYLAN EPD D.O.O.	HR
Cynt 0,4 mg filmom obložene tablete	not available	UP/I-530-09/11-01/317	MYLAN EPD D.O.O.	HR
Physiotens 0,2 mg filmom obložene tablete	not available	UP/I-530-09/10-02/264	MYLAN EPD D.O.O.	HR
Physiotens 0,4 mg filmom obložene tablete	not available	UP/I-530-09/10-02/265	MYLAN EPD D.O.O.	HR
Moksonidin Mylan 0,2 mg filmom obložene tablete	not available	UP/I-530-09/11-01/318	MYLAN EPD D.O.O.	HR
Moksonidin Mylan 0,4 mg filmom obložene tablete	not available	UP/I-530-09/11-01/319	MYLAN EPD D.O.O.	HR
Physiotens 0,2 mg filmtabletta	not available	OGYI-T-6365/01	MYLAN HEALTHCARE GMBH	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
Physiotens 0,3 mg filmtabletta	not available	OGYI-T-6365/04	MYLAN HEALTHCARE GMBH	HU
Physiotens 0,4 mg filmtabletta	not available	OGYI-T-6365/06	MYLAN HEALTHCARE GMBH	HU
FISIOTENS 0,2 mg compresse rivestite con film	not available	034063026	BGP PRODUCTS S.R.L.	IT
FISIOTENS 0,2 mg compresse rivestite con film	not available	034063014	BGP PRODUCTS S.R.L.	IT
FISIOTENS 0,3 mg compresse rivestite con film	not available	034063040	BGP PRODUCTS S.R.L.	IT
FISIOTENS 0,3 mg compresse rivestite con film	not available	034063038	BGP PRODUCTS S.R.L.	IT
FISIOTENS 0,4 mg compresse rivestite con film	not available	034063065	BGP PRODUCTS S.R.L.	IT
FISIOTENS 0,4 mg compresse rivestite con film	not available	034063053	BGP PRODUCTS S.R.L.	IT
physiotens 0,2 mg plèvele dengtos tabletės	not available	LT/1/97/1627/002	MYLAN HEALTHCARE GMBH	LT
physiotens 0,2 mg plèvele dengtos tabletės	not available	LT/1/97/1627/001	MYLAN HEALTHCARE GMBH	LT
physiotens 0,4 mg plèvele dengtos tabletės	not available	LT/1/97/1627/004	MYLAN HEALTHCARE GMBH	LT
physiotens 0,4 mg plèvele dengtos tabletės	not available	LT/1/97/1627/003	MYLAN HEALTHCARE GMBH	LT
Physiotens 0,2 mg apvalkotās tabletes	not available	00-0562	MYLAN HEALTHCARE GMBH	LV
Physiotens 0,4 mg apvalkotās tabletes	not available	00-0564	MYLAN HEALTHCARE GMBH	LV

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
Physiotens 0,2 mg tabletter, filmdrasjerte	not available	96-142	BGP PRODUCTS AS	NO
Physiotens 0,4 mg tabletter, filmdrasjerte	not available	96-144	BGP PRODUCTS AS	NO
Physiotens 0,2, 0,2 mg, tabletki powlekane	not available	4008	BGP PRODUCTS POLAND SP. Z.O.O.	PL
Physiotens 0,4, 0,4 mg, tabletki powlekane	not available	4010	BGP PRODUCTS POLAND SP. Z.O.O.	PL
Physiotens Tablets 200 micrograms	not available	MA1138/00501	BGP PRODUCTS LTD.	MT
Physiotens® Tablets 400 micrograms	not available	MA1138/00502	BGP PRODUCTS LTD.	MT
Physiotens 0,2 mg filmdragerad tablett	not available	13110	BGP PRODUCTS AB	SE
Physiotens 0,4 mg filmdragerad tablett	not available	13112	BGP PRODUCTS AB	SE
CYNT 0,3	not available	58/0373/03-S	BIOMIN, A.S.	SK
Physiotens® 0.2 mg, film- coated tablets	not available	19127	VARNAVAS HADJIPANAYIS LTD. (LATSIA)	CY
Physiotens® 0.3 mg, film- coated tablets	not available	19128	VARNAVAS HADJIPANAYIS LTD. (LATSIA)	CY
Physiotens® 0.4 mg, film- coated tablets	not available	19129	VARNAVAS HADJIPANAYIS LTD. (LATSIA)	CY
CYNT 0,4	not available	58/0374/03-S	BIOMIN, A.S.	SK
CYNT 0,2	not available	58/0372/03-S	BIOMIN, A.S.	SK
Physiotens Tablets 200 micrograms	not available	PL 46302/0045	MYLAN PRODUCTS LIMITED	UK

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Physiotens® Tablets 300 micrograms	not available	PL 46302/0046	MYLAN PRODUCTS LIMITED	UK
Physiotens® Tablets 400 micrograms	not available	PL 46302/0047	MYLAN PRODUCTS LIMITED	UK
Physiotens 0,4 mg, õhukese polümeerikattega tabletid	not available	395102	MYLAN HEALTHCARE GMBH	EE
Physiotens 0,2 mg kalvopäällysteinen tabletti	not available	12352	MYLAN FINLAND OY	FI
Physiotens 0,4 mg kalvopäällysteinen tabletti	not available	12354	MYLAN FINLAND OY	FI
MOXON 0,2 mg Filmtabletten	not available	2005098212	MYLAN EPD SPRL	LU
MOXON 0,3 mg Filmtabletten	not available	2005098213	MYLAN EPD SPRL	LU
MOXON 0,4 mg Filmtabletten	not available	2005098214	MYLAN EPD SPRL	LU
MOXON 0,3 mg filmomhulde tabletten	not available	BE199613	MYLAN EPD SPRL	BE
MOXON 0,3 mg Filmtabletten	not available	BE199613	MYLAN EPD SPRL	BE
MOXON 0,2 mg filmomhulde tabletten	not available	BE168822	MYLAN EPD SPRL	BE
MOXON 0,2 mg Filmtabletten	not available	BE168822	MYLAN EPD SPRL	BE
MOXON 0,4 mg filmomhulde tabletten	not available	BE199622	MYLAN EPD SPRL	BE
MOXON 0,4 mg Filmtabletten	not available	BE199622	MYLAN EPD SPRL	BE
Moxonibene 0,2 mg-Filmtabletten	not available	1-19606	RATIOPHARM ARZNEIMITTEL VERTRIEBS-GMBH	AT

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Moxonibene 0,4 mg- Filmtabletten	not available	1-19608	RATIOPHARM ARZNEIMITTEL VERTRIEBS-GMBH	AT