



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 March 2017
EMA/173237/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: tamsulosin

Procedure no.: PSUSA/00002847/201607

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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
Alna® Ocas® 0,4 mg Retardtabletten	NL/H/0555/001	61324.00.00	BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG	DE
Alna® retard 0,4 mg - Kapseln	not available	1-21580	BOEHRINGER INGELHEIM RCV GMBH & CO KG	AT
Flomax◆ MR	not available	PL 00166/0171	ASTELLAS PHARMA LTD.	UK
Flomax Relief® MR	not available	PL 00015/0280	BOEHRINGER INGELHEIM LTD.	UK
Flomaxtra® XL, 400 micrograms, film-coated prolonged release tablet	not available	PL 00166/0199	ASTELLAS PHARMA LTD.	UK
JOSIR L.P. 0,4 mg, microgranules à libération prolongée en gélule	not available	34009 339 982 4 0	BOEHRINGER INGELHEIM FRANCE S.A.S	FR
Mapelor 0,4 capsules met gereguleerde afgifte, hard, 0,4 mg	NL/H/0106/001	RVG 19720	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	NL
Mapelor Ocas 0,4, tabletten met verlengde afgifte, filmomhuld	NL/H/0555/001	RVG 30687	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	NL
MECIR L.P. 0,4 mg, comprimé pelliculé à libération prolongée	not available	34009 369 625 5 2	BOEHRINGER INGELHEIM FRANCE S.A.S	FR
OMEXEL L.P. 0,4 mg, comprimé pelliculé à libération prolongée	not available	3400936962491	ASTELLAS PHARMA 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
Omic Ocas 0,4 Tabletten mit verzögerter Wirkstofffreigabe (Filmtabletten) 0,4 mg Tamsulosin-Hydrochlorid	NL/H/0554/001	BE 274784	ASTELLAS PHARMA B.V., OFFICE BE	BE
Omic Ocas 0,4, comprimés à libération prolongée, pelliculés	NL/H/0554/001	BE274784	ASTELLAS PHARMA B.V., OFFICE BE	BE
Omic Ocas 0,4, comprimés à libération prolongée, pelliculés	NL/H/0554/001	0566/10010680	ASTELLAS PHARMA B.V., OFFICE BE	LU
Omic Ocas 0,4, tabletten met verlengde afgifte, filmomhuld	NL/H/0554/001	BE 274784	ASTELLAS PHARMA B.V., OFFICE BE	BE
OMIX L.P. 0,4 mg, microgranules ♦ lib♦eration prolong♦e en g♦olule	not available	3400933998189	ASTELLAS PHARMA SAS	FR
Omnixel®, 400 micrograms, prolonged release tablets, film-coated	NL/H/0554/001	PA 1241/006/001	ASTELLAS PHARMA CO. LTD.	IE
Omnice	not available	16736	ASTELLAS PHARMA A/S	DK
OMNIC 0,4	not available	R/7164	ASTELLAS PHARMA SP.Z.O.O.	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
Omnice 0,4 cápsulas duras de liberación modificada	NL/H/0105/001	61.426	ASTELLAS PHARMA S.A.	ES
Omnice 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647036	ASTELLAS PHARMA S.P.A.	IT
Omnice 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647048	ASTELLAS PHARMA S.P.A.	IT
Omnice 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647149	ASTELLAS PHARMA S.P.A.	IT
Omnice 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647063	ASTELLAS PHARMA S.P.A.	IT
Omnice 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647051	ASTELLAS PHARMA S.P.A.	IT
Omnice 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647087	ASTELLAS PHARMA S.P.A.	IT
Omnice 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647152	ASTELLAS PHARMA S.P.A.	IT
Omnice 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647075	ASTELLAS PHARMA S.P.A.	IT

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
Omnic 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647113	ASTELLAS PHARMA S.P.A.	IT
Omnic 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647099	ASTELLAS PHARMA S.P.A.	IT
Omnic 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647101	ASTELLAS PHARMA S.P.A.	IT
Omnic 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647125	ASTELLAS PHARMA S.P.A.	IT
Omnic 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647137	ASTELLAS PHARMA S.P.A.	IT
Omnic 0,4 mg depottabletter	not available	04-2722	ASTELLAS PHARMA A/S	NO
Omnic 0,4 mg hörð hylki með breyttan losunarhraða	not available	980024	ASTELLAS PHARMA A/S	IS
Omnic 0,4 mg kapsel med modifierad frisättning, hård	not available	11819	ASTELLAS PHARMA A/S	FI
Omnic 0,4 mg módosított hatóanyagleadású kemény kapszula	not available	OGYI-T-5975/01	ASTELLAS PHARMA KFT	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
Omnice 0,4 mg säädellysti vapauttava kapseli, kova	not available	11819	ASTELLAS PHARMA A/S	FI
Omnice 0,4 mg, capsule rigide a rilascio modificato	NL/H/0105/001	032647024/M	ASTELLAS PHARMA S.P.A.	IT
Omnice 0,4 mg, capsule rigide a rilascio modificato	NL/H/0105/001	032647012/M	ASTELLAS PHARMA S.P.A.	IT
Omnice 0,4 mg, comprimidos de libertação prolongada, revestidos por película	NL/H/0554/001	5502489	ASTELLAS FARMA LDA.	PT
Omnice 0,4 mg, comprimidos de libertação prolongada, revestidos por película	NL/H/0554/001	5502588	ASTELLAS FARMA LDA.	PT
Omnice 0,4, capsules met gereguleerde afgifte, hard, 0,4 mg	NL/H/0105/001	RVG 17931	ASTELLAS PHARMA EUROPE B.V.	NL
Omnice Ocas 0,4 mg depottablett	not available	19557	ASTELLAS PHARMA A/S	FI
Omnice Ocas 0,4 mg depottabletti	not available	19557	ASTELLAS PHARMA A/S	FI
Omnice Ocas 0,4 mg filmom obložene tablete s produljenim	not available	UP/I-530-09/13-02/126	ASTELLAS D.O.O.	HR

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
oslobadanjem				
OMNIC OCAS 0,4 mg filmsko obložene tablete s podaljšanim sproščanjem	not available	5363-I-626/13	ASTELLAS PHARMA D.O.O.	SI
Omnice Ocas 0,4 mg, comprimidos de liberación prolongada recubiertos con película	NL/H/0554/001	66.678	ASTELLAS PHARMA S.A.	ES
Omnice Ocas 0,4, prolonged release tablets, film-coated	not available	MA067/00602	ASTELLAS PHARMA EUROPE B.V.	MT
Omnice Ocas 0,4, tabletten met verlengde afgifte, filmomhuld	NL/H/0554/001	RVG 30565	ASTELLAS PHARMA EUROPE B.V.	NL
Omnice Ocas 0,4; 0,4 mg, tabletki powlekane o przedłużonym uwalnianiu	NL/H/0554/001	11429	ASTELLAS PHARMA SP.Z.O.O.	PL
Omnice TOCAS 0,4	not available	87/005/05-C	ASTELLAS PHARMA S.R.O.	CZ
OMNICE TOCAS 0,4	not available	6775/2014/01	ASTELLAS PHARMA EUROPE B.V.	RO
Omnice TOCAS 0,4	not available	77/0029/05-S	ASTELLAS PHARMA S.R.O.	SK

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
Omnic Tocas 0,4 mg retard filmtabletta	not available	OGYI-T-9839/01	ASTELLAS PHARMA KFT	HU
OMNIC® 0,4 mg kapsule s produljenim oslobađanjem, tvrde	not available	HR-H-896410977	ASTELLAS D.O.O.	HR
Omnic® 0,4 mg modified release capsules	not available	MA067/00601	ASTELLAS PHARMA EUROPE B.V.	MT
OMNIC® 0,4 mg καψάκια ελεγχόμενης αποδέσμευσης, σκληρά	not available	8491/06-02-2007	ASTELLAS PHARMACEUTICALS A.E.B.E.	GR
OMNIC® 0,4mg καψάκια ελεγχόμενης αποδέσμευσης, σκληρά	NL/H/0105/001	22169/25-5-2015	ASTELLAS PHARMACEUTICALS A.E.B.E.	CY
Omnic® Ocas® 0,4 mg Retardtabletten	NL/H/0554/001	61337.00.00	ASTELLAS PHARMA GMBH	DE
OMNIC® TOCAS	not available	28007 (3/5/2006)	ASTELLAS PHARMACEUTICALS A.E.B.E.	GR
Pradif 0,4 mg capsule rigide a rilascio modificato	NL/H/0106/001	030106013	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	IT
Pradif 0,4 mg capsule rigide a rilascio modificato	NL/H/0106/001	030106025	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	IT

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
Pradif, 0,4 mg, comprimidos de libertação prolongada revestidos por película	NL/H/0555/001	5504485	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	PT
Pradif, 0,4 mg, comprimidos de libertação prolongada revestidos por película	NL/H/0555/001	5504584	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	PT
PRADIF® OCAS 0,4 mg δισκία παρατεταμένης αποδέσμευσης	not available	41103/07	BOEHRINGER INGELHEIM ELLAS AE	GR
TAMFREX XL 400 microgram capsules	PT/H/0562/001	PL 16363/0254	MILPHARM LIMITED	UK
Tamsu-astellas 0,4 mg Hartkapsel mit veränderter Wirkstofffreisetzung	NL/H/0528/001	61424.00.00	ASTELLAS PHARMA GMBH	DE
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	5191/2012/01	AUROBINDO PHARMA (MALTA) LIMITED	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	5191/2012/02	AUROBINDO PHARMA (MALTA) LIMITED	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	5191/2012/03	AUROBINDO PHARMA (MALTA) LIMITED	RO

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
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	5191/2012/04	AUROBINDO PHARMA (MALTA) LIMITED	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	5191/2012/05	AUROBINDO PHARMA (MALTA) LIMITED	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	5191/2012/06	AUROBINDO PHARMA (MALTA) LIMITED	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	5191/2012/07	AUROBINDO PHARMA (MALTA) LIMITED	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	5191/2012/08	AUROBINDO PHARMA (MALTA) LIMITED	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	5191/2012/09	AUROBINDO PHARMA (MALTA) LIMITED	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	5191/2012/10	AUROBINDO PHARMA (MALTA) LIMITED	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	5191/2012/11	AUROBINDO PHARMA (MALTA) LIMITED	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	5191/2012/12	AUROBINDO PHARMA (MALTA) LIMITED	RO

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Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	5191/2012/13	AUROBINDO PHARMA (MALTA) LIMITED	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	5191/2012/14	AUROBINDO PHARMA (MALTA) LIMITED	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	5191/2012/15	AUROBINDO PHARMA (MALTA) LIMITED	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	5191/2012/16	AUROBINDO PHARMA (MALTA) LIMITED	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	5191/2012/17	AUROBINDO PHARMA (MALTA) LIMITED	RO
Tamsulosina Astellas Pharma Europe 0,4 mg, capsule rigide a rilascio modificato	NL/H/0528/001	037020017	ASTELLAS PHARMA EUROPE B.V.	IT
Tamsulosina Astellas Pharma Europe 0,4 mg, capsule rigide a rilascio modificato	NL/H/0528/001	037020031	ASTELLAS PHARMA EUROPE B.V.	IT
Tamsulosina Astellas Pharma Europe 0,4 mg, capsule rigide a rilascio modificato	NL/H/0528/001	037020029	ASTELLAS PHARMA EUROPE B.V.	IT

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
Tamsulosina Astellas Pharma Europe 0,4 mg, capsule rigide a rilascio modificato	NL/H/0528/001	037020043	ASTELLAS PHARMA EUROPE B.V.	IT
Tamsulosina Astellas Pharma Europe 0,4 mg, capsule rigide a rilascio modificato	NL/H/0528/001	037020056	ASTELLAS PHARMA EUROPE B.V.	IT
Tamsulosina Astellas Pharma Europe 0,4 mg, capsule rigide a rilascio modificato	NL/H/0528/001	037020068	ASTELLAS PHARMA EUROPE B.V.	IT
Tamsulosina Astellas Pharma Europe 0,4 mg, capsule rigide a rilascio modificato	NL/H/0528/001	037020082	ASTELLAS PHARMA EUROPE B.V.	IT
Tamsulosina Astellas Pharma Europe 0,4 mg, capsule rigide a rilascio modificato	NL/H/0528/001	037020094	ASTELLAS PHARMA EUROPE B.V.	IT
Tamsulosina Astellas Pharma Europe 0,4 mg, capsule rigide a rilascio modificato	NL/H/0528/001	037020070/M	ASTELLAS PHARMA EUROPE B.V.	IT
Tamsulosine Hydrochloride Yamanouchi Pharma, 0,4 mg, Capsules met	NL/H/0528/001	BE278713	ASTELLAS PHARMA EUROPE B.V.	BE

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gereguleerde afgifte, hard				
Tamsulosine Hydrochloride Yamanouchi Pharma, 0,4 mg, Capsules met gereguleerde afgifte, hard	NL/H/0528/001	BE278704	ASTELLAS PHARMA EUROPE B.V.	BE
Tamsulosine Hydrochloride Yamanouchi Pharma, 0,4 mg, Hartkapsel mit veränderter Wirkstofffreisetzung	NL/H/0528/001	BE278713	ASTELLAS PHARMA EUROPE B.V.	BE
Tamsulosine Hydrochloride Yamanouchi Pharma, 0,4 mg, Hartkapsel mit veränderter Wirkstofffreisetzung	NL/H/0528/001	BE278704	ASTELLAS PHARMA EUROPE B.V.	BE
Tamsulosine Hydrochloride Yamanouchi Pharma, 0,4, gélule à libération modifiée	NL/H/0528/001	BE278713	ASTELLAS PHARMA EUROPE B.V.	BE
Tamsulosine Hydrochloride Yamanouchi Pharma, 0,4,	NL/H/0528/001	BE278704	ASTELLAS PHARMA EUROPE B.V.	BE

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gélule à libération modifiée				
Tamsulosine Hydrochloride Yamanouchi Pharma, 0,4, gélule à libération modifiée	NL/H/0528/001	1681/06050028	ASTELLAS PHARMA EUROPE B.V.	LU
Tamsulosini Hydrochloridum	NL/H/0528/001	RVG 29682	ASTELLAS PHARMA EUROPE B.V.	NL
UROLOSIN 0,4 mg cápsulas duras de liberación modificada	NL/H/0106/001	61.425	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	ES
UROLOSIN OCAS 0,4 mg comprimidos de liberación prolongada recubiertos con película	NL/H/0555/001	66.677	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	ES
Омник Токас 0,4 mg таблетки с удължено освобождаване	not available	20050320	ASTELLAS PHARMA D.O.O.	BG