



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 February 2022
EMA/103393/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: tamsulosin

Procedure no.: EMEA/H/C/PSUSA/00002847/202107

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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
Flomaxtra XL, 400 micrograms, film-coated prolonged-release tablet	not available	PL 00166/0199	ASTELLAS PHARMA LTD.	XI
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	369 624 – 9	ASTELLAS PHARMA SAS	FR
Omic Ocas 0,4 Filmtabletten mit verzögerter Wirkstofffreigabe 0,4 mg	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	2010010680	ASTELLAS PHARMA B.V., OFFICE BE	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
Omic Ocas 0,4, comprimés pelliculés à libération prolongée.	NL/H/0554/001	BE 274784	ASTELLAS PHARMA B.V., OFFICE BE	BE
Omic Ocas 0,4, filmomhulde tabletten met verlengde afgifte.	NL/H/0554/001	BE 274784	ASTELLAS PHARMA B.V., OFFICE BE	BE
OMIX L.P. 0,4 mg, microgranules à libération prolongée en gélule	not available	3400933998189	ASTELLAS PHARMA SAS	FR
Omnixel, 400 micrograms prolonged release tablets, film-coated	NL/H/0554/001	PA1241/006/001	ASTELLAS PHARMA CO. LTD.	IE
Omnix 0,4 cápsulas duras de liberación modificada	NL/H/0105/001	61.426	ASTELLAS PHARMA S.A.	ES
Omnix 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647036	ASTELLAS PHARMA S.P.A.	IT
Omnix 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647048	ASTELLAS PHARMA S.P.A.	IT
Omnix 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647149	ASTELLAS PHARMA S.P.A.	IT
Omnix 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647063	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
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
Omnice 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647113	ASTELLAS PHARMA S.P.A.	IT
Omnice 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647099	ASTELLAS PHARMA S.P.A.	IT
Omnice 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647101	ASTELLAS PHARMA S.P.A.	IT
Omnice 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647125	ASTELLAS PHARMA S.P.A.	IT
Omnice 0,4 mg compresse a rilascio prolungato rivestite con film	NL/H/0554/001	032647137	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
Omnice 0,4 mg depottabletter	not available	04-2722	ASTELLAS PHARMA A/S	NO
Omnice 0,4 mg hård kapsel med modifierad frisättning	not available	11819	ASTELLAS PHARMA A/S	FI
Omnice 0,4 mg hörð hylki með breyttan losunarhraða	not available	980024	ASTELLAS PHARMA A/S	IS
Omnice 0,4 mg módosított hatóanyagleadású kemény kapszula	not available	OGYI-T-5975/01	ASTELLAS PHARMA KFT	HU
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	NL/H/0554/001	5502588	ASTELLAS FARMA LDA.	PT

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libertação prolongada, revestidos por película				
Omnice 0,4, 0,4 mg, kapsułki o zmodyfikowanym uwalnianiu, twarde (-)	not available	R/7164	ASTELLAS PHARMA SP.Z.O.O.	PL
Omnice 0,4, 0.4 mg, modified release capsules, hard	not available	MA1387/00101	ASTELLAS PHARMACEUTICALS A.E.B.E.	MT
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 comprimidos de liberación prolongada recubiertos con película	NL/H/0554/001	66.678	ASTELLAS PHARMA S.A.	ES
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 filmsko obložene tablete s podaljšanim sproščanjem	not available	5363-I-626/13	ASTELLAS PHARMA D.O.O.	SI

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 Ocas 0,4 mg Retardtabletten	NL/H/0554/001	61337.00.00	ASTELLAS PHARMA GMBH	DE
Omnice Ocas 0,4 mg tablete s produljenim oslobađanjem	not available	HR-H-245554985	ASTELLAS D.O.O.	HR
Omnice Ocas 0,4, prolonged release tablets, film-coated	not available	MA1387/00102	ASTELLAS PHARMACEUTICALS A.E.B.E.	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 przedluzonym uwalnianiu	NL/H/0554/001	11 429	ASTELLAS PHARMA SP.Z.O.O.	PL
OMNICE TOCAS 0,4 mg comprimate cu eliberare prelungita	not available	6775/2014/01	ASTELLAS PHARMA EUROPE B.V.	RO
Omnice Tocas 0,4 mg retard filmtabletta	not available	OGYI-T-9839/01	ASTELLAS PHARMA KFT	HU
Omnice Tocas 0,4 mg tablety s prodlouzenym uvolnovanim	not available	87/005/05-C	ASTELLAS PHARMA S.R.O.	CZ
Omnice TOCAS 0,4 tablety s predizenym uvolnovanim	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 δισκία παρατεταμένης αποδέσμευσης	NL/H/0554/001	022184	ASTELLAS PHARMACEUTICALS A.E.B.E.	CY
OMNIC TOCAS® 0,4 mg δισκία παρατεταμένης αποδέσμευσης	not available	47402/11/20-04-2012	ASTELLAS PHARMACEUTICALS A.E.B.E.	GR
OMNIC TOCAS® 0,4 mg δισκία παρατεταμένης αποδέσμευσης	not available	47402/11/20-04-2012	ASTELLAS PHARMACEUTICALS A.E.B.E.	GR
OMNIC TOCAS® 0,4 mg δισκία παρατεταμένης αποδέσμευσης	not available	47402/11/20-04-2012	ASTELLAS PHARMACEUTICALS A.E.B.E.	GR
OMNIC TOCAS® 0,4 mg δισκία παρατεταμένης αποδέσμευσης	not available	47402/11/20-04-2012	ASTELLAS PHARMACEUTICALS A.E.B.E.	GR
OMNIC TOCAS® 0,4 mg δισκία παρατεταμένης αποδέσμευσης	not available	47402/11/20-04-2012	ASTELLAS PHARMACEUTICALS A.E.B.E.	GR
Omnic, depotkapsler, hårde	not available	16736	ASTELLAS PHARMA A/S	DK
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

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
OMNICO,4 mg tvrde kapsule s prilagođenim oslobađanjem	not available	HR-H-896410977	ASTELLAS D.O.O.	HR
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
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	41103/07/17-03-2008	BOEHRINGER INGELHEIM ELLAS AE	GR
Tamiron, 0,4 mg, kapsułki o przedłużonym uwalnianiu, twarde	FI/H/0919/001	24028	ORION CORPORATION	PL
Tamsu-astellas 0,4 mg Hartkapsel mit veränderter Wirkstofffreisetzung	NL/H/0528/001	61424.00.00	ASTELLAS 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
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	10359/2017/01	AUROBINDO PHARMA ROMÂNIA S.R.L.	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	10359/2017/02	AUROBINDO PHARMA ROMÂNIA S.R.L.	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	10359/2017/03	AUROBINDO PHARMA ROMÂNIA S.R.L.	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	10359/2017/04	AUROBINDO PHARMA ROMÂNIA S.R.L.	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	10359/2017/05	AUROBINDO PHARMA ROMÂNIA S.R.L.	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	10359/2017/06	AUROBINDO PHARMA ROMÂNIA S.R.L.	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	10359/2017/07	AUROBINDO PHARMA ROMÂNIA S.R.L.	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	10359/2017/08	AUROBINDO PHARMA ROMÂNIA S.R.L.	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	10359/2017/09	AUROBINDO PHARMA ROMÂNIA S.R.L.	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	10359/2017/10	AUROBINDO PHARMA ROMÂNIA S.R.L.	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	10359/2017/11	AUROBINDO PHARMA ROMÂNIA S.R.L.	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	10359/2017/12	AUROBINDO PHARMA ROMÂNIA S.R.L.	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	10359/2017/13	AUROBINDO PHARMA ROMÂNIA S.R.L.	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	10359/2017/14	AUROBINDO PHARMA ROMÂNIA S.R.L.	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	10359/2017/15	AUROBINDO PHARMA ROMÂNIA S.R.L.	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	10359/2017/16	AUROBINDO PHARMA ROMÂNIA S.R.L.	RO
Tamsulosin Aurobindo 400 micrograme capsule cu eliberare prelungită	PT/H/0562/001	10359/2017/17	AUROBINDO PHARMA ROMÂNIA S.R.L.	RO
Tamsulosin US Pharmacia, 0,4 mg, tabletki o przedłużonym uwalnianiu	not available	25406	US PHARMACIA 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
Tamsulosine Hydrochloride Yamanouchi Pharma, 0,4 mg, Capsules met gereguleerde afgifte, hard	NL/H/0528/001	BE278713	ASTELLAS PHARMA EUROPE B.V.	BE
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

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
Tamsulosine Hydrochloride Yamanouchi Pharma, 0,4, gélule à libération modifiée	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	1681/06050028	ASTELLAS PHARMA EUROPE B.V.	LU
Tamsulosini Hydrochloridum capsules met gereguleerde afgifte, hard, 0,4 mg	NL/H/0528/001	RVG 29682	ASTELLAS PHARMA EUROPE B.V.	NL
Tamsurion 0,4 mg hårda depotkapslar	FI/H/0919/001	34279	ORION CORPORATION	FI
Tamsurion 0,4 mg kovat depotkapselit	FI/H/0919/001	34279	ORION CORPORATION	FI
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