14 February 2019
EMA/118055/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: solifenacin / tamsulosin

Procedure no.: PSUSA/00010285/201807

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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
Volutsa 6 mg + 0,4 mg comprimidos de libertação modificada	NL/H/3131/001	5615752	ASTELLAS FARMA LDA.	PT
Volutsa 6 mg/0,4 mg tabletten met gereguleerde afgifte	NL/H/3131/001	RVG 114181	ASTELLAS PHARMA EUROPE B.V.	NL
Volutsa 6 mg/0.4 mg compresse a rilascio modificato	NL/H/3131/001	043255102	ASTELLAS PHARMA S.P.A.	IT
Volutsa 6 mg/0.4 mg compresse a rilascio modificato	NL/H/3131/001	043255037	ASTELLAS PHARMA S.P.A.	IT
Volutsa 6 mg/0.4 mg compresse a rilascio modificato	NL/H/3131/001	043255013	ASTELLAS PHARMA S.P.A.	IT
Volutsa 6 mg/0.4 mg compresse a rilascio modificato	NL/H/3131/001	043255025	ASTELLAS PHARMA S.P.A.	IT
Volutsa 6 mg/0.4 mg compresse a rilascio modificato	NL/H/3131/001	043255049	ASTELLAS PHARMA S.P.A.	IT
Volutsa 6 mg/0.4 mg compresse a rilascio modificato	NL/H/3131/001	043255090	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
Volutsa 6 mg/0.4 mg compresse a rilascio modificato	NL/H/3131/001	043255088	ASTELLAS PHARMA S.P.A.	IT
Volutsa 6 mg/0.4 mg compresse a rilascio modificato	NL/H/3131/001	043255114	ASTELLAS PHARMA S.P.A.	IT
Volutsa 6 mg/0.4 mg compresse a rilascio modificato	NL/H/3131/001	043255064	ASTELLAS PHARMA S.P.A.	IT
Volutsa 6 mg/0.4 mg compresse a rilascio modificato	NL/H/3131/001	043255076	ASTELLAS PHARMA S.P.A.	IT
Volutsa 6 mg/0.4 mg compresse a rilascio modificato	NL/H/3131/001	043255052	ASTELLAS PHARMA S.P.A.	IT
Volutsa 6 mg/0,4 mg comprimidos de liberación modificada	NL/H/3131/001	78928	ASTELLAS PHARMA S.A.	ES
Urizia	NL/H/2968/001	52739	ASTELLAS PHARMA A/S	DK
Urizia 6 mg/0,4 mg säädellysti vapauttava tabletti	NL/H/2968/001	31656	ASTELLAS PHARMA A/S	FI

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
Urizia 6 mg/0,4 mg tabletter med modifierad frisättning	NL/H/2968/001	31656	ASTELLAS PHARMA A/S	FI
Vesomni 6 mg/0,4 mg módosított hatóanyag-leadású tabletta	NL/H/2968/001	OGYI-T-22691/11	ASTELLAS PHARMA KFT	HU
Urizia 6 mg/0,4 mg tafla með breyttan losunarhraða	NL/H/2968/001	IS/1/14/054/01	ASTELLAS PHARMA A/S	IS
Urizia 6 mg/ 0,4 mg ilgstošas darbibas tabletes	NL/H/2968/001	14-0146	ASTELLAS PHARMA A/S	LV
Vesomni 6 mg/0,4 mg módosított hatóanyag-leadású tabletta	NL/H/2968/001	OGYI-T-22691/02	ASTELLAS PHARMA KFT	HU
Vesomni 6 mg/0,4 mg módosított hatóanyag-leadású tabletta	NL/H/2968/001	OGYI-T-22691/04	ASTELLAS PHARMA KFT	HU
Vesomni 6 mg/0,4 mg módosított hatóanyag-leadású tabletta	NL/H/2968/001	OGYI-T-22691/06	ASTELLAS PHARMA KFT	HU
Vesomni 6 mg/0,4 mg módosított hatóanyag-leadású tabletta	NL/H/2968/001	OGYI-T-22691/03	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
Vesomni 6 mg/0,4 mg módosított hatóanyag-leadású tabletta	NL/H/2968/001	OGYI-T-22691/08	ASTELLAS PHARMA KFT	HU
Vesomni 6 mg/0,4 mg módosított hatóanyag-leadású tabletta	NL/H/2968/001	OGYI-T-22691/07	ASTELLAS PHARMA KFT	HU
Vesomni 6 mg/0,4 mg módosított hatóanyag-leadású tabletta	NL/H/2968/001	OGYI-T-22691/09	ASTELLAS PHARMA KFT	HU
Vesomni 6 mg/0,4 mg módosított hatóanyag-leadású tabletta	NL/H/2968/001	OGYI-T-22691/05	ASTELLAS PHARMA KFT	HU
Vesomni 6 mg/0,4 mg módosított hatóanyag-leadású tabletta	NL/H/2968/001	OGYI-T-22691/10	ASTELLAS PHARMA KFT	HU
Vesomni 6 mg/0,4 mg módosított hatóanyag-leadású tabletta	NL/H/2968/001	OGYI-T-22691/01	ASTELLAS PHARMA KFT	HU
Vesomni 6 mg + 0,4 mg comprimidos de libertação modificada	NL/H/2968/001	5615810	ASTELLAS FARMA LDA.	PT
Везомни 6 mg/0,4 mg таблетки с изменено освобождаване	NL/H/2968/001	20140211 / 07.07.201	ASTELLAS PHARMA D.O.O.	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
Vesomni 6 mg/0,4 mg tablete s prilagođenim oslobađanjem	NL/H/2968/001	HR-H-310582492	ASTELLAS D.O.O.	HR
Vesomni 6 mg/0,4 mg comprimés à libération modifiée	NL/H/2968/001	2014040060	ASTELLAS PHARMA EUROPE B.V.	LU
Vesomni (6+0,4) mg/tab δισκία ελεγχόμενης αποδέσμευσης	NL/H/2968/001	50321/11-6-2014	ASTELLAS PHARMACEUTICALS A.E.B.E.	GR
Vesomni 6 mg/0,4 mg tablete s prirejenim sproščanjem	NL/H/2968/001	H/14/01635/001	ASTELLAS PHARMA D.O.O.	SI
Vesomni 6 mg/0.4 mg compresse a rilascio modificato	NL/H/2968/001	043254061	ASTELLAS PHARMA S.P.A.	IT
Vesomni 6 mg/0.4 mg compresse a rilascio modificato	NL/H/2968/001	043254097	ASTELLAS PHARMA S.P.A.	IT
Vesomni 6 mg/0.4 mg compresse a rilascio modificato	NL/H/2968/001	043254085	ASTELLAS PHARMA S.P.A.	IT
Vesomni 6 mg/0.4 mg compresse a rilascio modificato	NL/H/2968/001	043254046	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
Vesomni 6 mg/0.4 mg compresse a rilascio modificato	NL/H/2968/001	043254059	ASTELLAS PHARMA S.P.A.	IT
Vesomni 6 mg/0.4 mg compresse a rilascio modificato	NL/H/2968/001	043254022	ASTELLAS PHARMA S.P.A.	IT
Vesomni 6 mg/0.4 mg compresse a rilascio modificato	NL/H/2968/001	043254034	ASTELLAS PHARMA S.P.A.	IT
Vesomni 6 mg/0.4 mg compresse a rilascio modificato	NL/H/2968/001	043254073	ASTELLAS PHARMA S.P.A.	IT
Vesomni 6 mg/0.4 mg compresse a rilascio modificato	NL/H/2968/001	043254109	ASTELLAS PHARMA S.P.A.	IT
Vesomni 6 mg/0.4 mg compresse a rilascio modificato	NL/H/2968/001	043254010	ASTELLAS PHARMA S.P.A.	IT
Vesomni 6 mg/0.4 mg compresse a rilascio modificato	NL/H/2968/001	043254111	ASTELLAS PHARMA S.P.A.	IT
Vesomni 6 mg/0,4 mg Tabletten mit veränderter Wirkstofffreisetzung	NL/H/2968/001	BE445067	ASTELLAS PHARMA B.V., OFFICE BE	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
Vesomni 6 mg/0,4 mg comprimidos de liberación modificada	NL/H/2968/001	78607	ASTELLAS PHARMA S.A.	ES
Urizia 6 mg/0,4 mg tabletter med modifisert frisetting	NL/H/2968/001	13-9641	ASTELLAS PHARMA A/S	NO
Vesomni 6 mg/0,4 mg comprimés à libération modifiée	NL/H/2968/001	BE445067	ASTELLAS PHARMA B.V., OFFICE BE	BE
Urizia 6 mg/0,4 mg modifikuoto atpalaidavimo tabletės	NL/H/2968/001	LT/1/14/3606/009	ASTELLAS PHARMA A/S	LT
Urizia 6 mg/0,4 mg modifikuoto atpalaidavimo tabletės	NL/H/2968/001	LT/1/14/3606/010	ASTELLAS PHARMA A/S	LT
Urizia 6 mg/0,4 mg modifikuoto atpalaidavimo tabletės	NL/H/2968/001	LT/1/14/3606/011	ASTELLAS PHARMA A/S	LT
Urizia 6 mg/0,4 mg modifikuoto atpalaidavimo tabletės	NL/H/2968/001	LT/1/14/3606/001	ASTELLAS PHARMA A/S	LT
Urizia 6 mg/0,4 mg modifikuoto atpalaidavimo tabletės	NL/H/2968/001	LT/1/14/3606/004	ASTELLAS PHARMA A/S	LT

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
Urizia 6 mg/0,4 mg modifikuoto atpalaidavimo tabletės	NL/H/2968/001	LT/1/14/3606/006	ASTELLAS PHARMA A/S	LT
Urizia 6 mg/0,4 mg modifikuoto atpalaidavimo tabletės	NL/H/2968/001	LT/1/14/3606/007	ASTELLAS PHARMA A/S	LT
Urizia 6 mg/0,4 mg modifikuoto atpalaidavimo tabletės	NL/H/2968/001	LT/1/14/3606/008	ASTELLAS PHARMA A/S	LT
Urizia 6 mg/0,4 mg modifikuoto atpalaidavimo tabletės	NL/H/2968/001	LT/1/14/3606/005	ASTELLAS PHARMA A/S	LT
Urizia, 6 mg/0,4 mg toimeainet modifitseeritult vabastavad tabletid	NL/H/2968/001	847214	ASTELLAS PHARMA A/S	EE
Vesomni, 6 mg+0,4 mg, tabletki o zmodyfikowanym uwalnianiu	NL/H/2968/001	22142	ASTELLAS PHARMA SP.Z.O.O.	PL
Urizia 6 mg/0,4 mg modifikuoto atpalaidavimo tabletės	NL/H/2968/001	LT/1/14/3606/003	ASTELLAS PHARMA A/S	LT

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
Urizia 6 mg/0,4 mg modifikuoto atpalaidavimo tabletės	NL/H/2968/001	LT/1/14/3606/002	ASTELLAS PHARMA A/S	LT
Vesomni 6 mg/0,4 mg comprimate cu eliberare modificată	NL/H/2968/001	6661/2014/04	ASTELLAS PHARMA D.O.O.	RO
Vesomni 6 mg/0,4 mg comprimate cu eliberare modificată	NL/H/2968/001	6661/2014/10	ASTELLAS PHARMA D.O.O.	RO
Vesomni 6 mg/0,4 mg comprimate cu eliberare modificată	NL/H/2968/001	6661/2014/02	ASTELLAS PHARMA D.O.O.	RO
Vesomni 6 mg/0,4 mg comprimate cu eliberare modificată	NL/H/2968/001	6661/2014/05	ASTELLAS PHARMA D.O.O.	RO
Vesomni 6 mg/0,4 mg comprimate cu eliberare modificată	NL/H/2968/001	6661/2014/06	ASTELLAS PHARMA D.O.O.	RO
Vesomni 6 mg/0,4 mg comprimate cu eliberare modificată	NL/H/2968/001	6661/2014/03	ASTELLAS PHARMA D.O.O.	RO
Vesomni 6 mg/0,4 mg comprimate cu eliberare modificată	NL/H/2968/001	6661/2014/08	ASTELLAS PHARMA D.O.O.	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
Vesomni 6 mg/0,4 mg comprimate cu eliberare modificată	NL/H/2968/001	6661/2014/01	ASTELLAS PHARMA D.O.O.	RO
Vesomni 6 mg/0,4 mg comprimate cu eliberare modificată	NL/H/2968/001	6661/2014/07	ASTELLAS PHARMA D.O.O.	RO
Vesomni 6 mg/0,4 mg comprimate cu eliberare modificată	NL/H/2968/001	6661/2014/11	ASTELLAS PHARMA D.O.O.	RO
Vesomni 6 mg/0,4 mg comprimate cu eliberare modificată	NL/H/2968/001	6661/2014/09	ASTELLAS PHARMA D.O.O.	RO
Vesomni 6 mg/0,4 mg tabletten met gereguleerde afgifte	NL/H/2968/001	RVG 111622	ASTELLAS PHARMA EUROPE B.V.	NL
Vesomni 6 mg/0,4 mg tabletten met gereguleerde afgifte	NL/H/2968/001	BE445067	ASTELLAS PHARMA B.V., OFFICE BE	BE
Vesomni 6 mg/0,4 mg tablety s riadeným uvoľňovaním	NL/H/2968/001	77/0409/13-S	ASTELLAS PHARMA S.R.O.	SK
Urizia 6 mg/0,4 mg tabletter med modifierad frisättning	NL/H/2968/001	49635	ASTELLAS PHARMA A/S	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
Vesomni 6 mg/0.4 mg modified release tablets	NL/H/2968/001	PA1241/016/001	ASTELLAS PHARMA CO. LTD.	IE
Vesomni 6 mg/0.4 mg modified release tablets	NL/H/2968/001	PL 00166/0404	ASTELLAS PHARMA LTD.	UK
Urizia 6 mg/0,4 mg tablety s rízeným uvolnováním	NL/H/2968/001	73/439/13-C	ASTELLAS PHARMA S.R.O.	CZ
Vesomni 6 mg/0,4 mg Tabletten mit veränderter Wirkstofffreisetzung	NL/H/2968/001	135278	ASTELLAS PHARMA GES.M.B.H.	AT