



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 July 2019
EMA/403763/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: terazosin

Procedure no.: PSUSA/00002895/201811

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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
URODIE 2 mg compresse	not available	028284014	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
URODIE 5 mg compresse	not available	028284026	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
URODIE 10 mg compresse	not available	028284053	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
URODIE 2,5 mg/ml Gocce Orali, Soluzione	not available	028284040	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
Flotrin® Max 10 mg, Tabletten	not available	29390.02.00	MIBE GMBH ARZNEIMITTEL	DE
Flotrin® Pro 2 mg, Tabletten	not available	29390.00.00	MIBE GMBH ARZNEIMITTEL	DE
Flotrin® Uro 5 mg, Tabletten	not available	29390.01.00	MIBE GMBH ARZNEIMITTEL	DE
ITRIN 2 MG COMPRESSE	not available	026929024	ECUPHARMA S.R.L.	IT
ITRIN 5 MG COMPRESSE	not available	026929036	ECUPHARMA S.R.L.	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
Hytrin Tablets 1mg	not available	MA625/00101	AMDIPHARM LIMITED	MT
Hytrin Tablets 5mg	not available	MA625/00103	AMDIPHARM LIMITED	MT
Hytrin Tablets 10mg	not available	MA625/00104	AMDIPHARM LIMITED	MT
Hytrin Tablets 2mg	not available	MA625/00102	AMDIPHARM LIMITED	MT
UNOPROST 5 mg compresse	not available	028652028	LABORATORI GUIDOTTI S.P.A.	IT
UNOPROST 10 mg compresse	not available	028652081	LABORATORI GUIDOTTI S.P.A.	IT
UNOPROST 2 mg compresse	not available	028652016	LABORATORI GUIDOTTI S.P.A.	IT
HYTRINE 1 mg, comprimé	not available	340 476.1	AMDIPHARM LIMITED	FR
HYTRINE 1 mg, comprimé	not available	330 110.4	AMDIPHARM LIMITED	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
HYTRINE 5 mg, comprimé	not available	330 112.7	AMDIPHARM LIMITED	FR
Hytrin 10mg Tablets	not available	PA 1142/5/4	AMDIPHARM LIMITED	IE
Hytrin 5mg Tablets	not available	PA 1142/5/3	AMDIPHARM LIMITED	IE
Hytrin 2mg Tablets	not available	PA 1142/5/2	AMDIPHARM LIMITED	IE
Hytrin 5 mg tabletten	not available	BE 138092	AMDIPHARM LIMITED	BE
Hytrin 5 mg comprimés	not available	BE 138092	AMDIPHARM LIMITED	BE
Hytrin 1 mg Tabletten	not available	BE 138047	AMDIPHARM LIMITED	BE
Hytrin 2 mg Tabletten	not available	BE 138101	AMDIPHARM LIMITED	BE
Hytrin 5 mg Tabletten	not available	BE 138092	AMDIPHARM LIMITED	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
Hytrin 10 mg Tabletten	not available	BE 138031	AMDIPHARM LIMITED	BE
H Y T R I N	not available	15782/15/15-11-2016	AMDIPHARM LIMITED	GR
H Y T R I N	not available	16408/15/15-11-2016	AMDIPHARM LIMITED	GR
Terazosab 1 mg tabletten	not available	BE 220035	AMDIPHARM LIMITED	BE
Terazosab 2 mg tabletten	not available	BE 220044	AMDIPHARM LIMITED	BE
Terazosab 5 mg tabletten	not available	BE 220053	AMDIPHARM LIMITED	BE
Terazosab 10 mg tabletten	not available	BE 220062	AMDIPHARM LIMITED	BE
Vicard 2 mg-Tabletten	not available	1-18685	AMDIPHARM LIMITED	AT
Vicard 5 mg-Tabletten	not available	1-18684	AMDIPHARM LIMITED	AT

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
Uroflo 2 mg-Tabletten	not available	1-20342	AMDIPHARM LIMITED	AT
Uroflo 5 mg-Tabletten	not available	1-20341	AMDIPHARM LIMITED	AT
Hytrin 1mg and 2mg Tablets (Starter Pack)	not available	PA 1142/5/1	AMDIPHARM LIMITED	IE
Hytrin 10 mg comprimés	not available	BE 138031	AMDIPHARM LIMITED	BE
Hytrin 10 mg tabletten	not available	BE 138031	AMDIPHARM LIMITED	BE
Hytrin 1 mg comprimés	not available	BE 138047	AMDIPHARM LIMITED	BE
Hytrin 1 mg tabletten	not available	BE 138047	AMDIPHARM LIMITED	BE
Hytrin 2 mg comprimés	not available	BE 138101	AMDIPHARM LIMITED	BE
Hytrin 2 mg tabletten	not available	BE 138101	AMDIPHARM LIMITED	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
Terazosab 1 mg comprimés	not available	BE 220035	AMDIPHARM LIMITED	BE
Terazosab 1 mg tabletten	not available	BE 220035	AMDIPHARM LIMITED	BE
Terazosab 2 mg comprimés	not available	BE 220044	AMDIPHARM LIMITED	BE
Terazosab 2 mg tabletten	not available	BE 220044	AMDIPHARM LIMITED	BE
Terazosab 5 mg comprimés	not available	BE 220053	AMDIPHARM LIMITED	BE
Terazosab 5 mg tabletten	not available	BE 220053	AMDIPHARM LIMITED	BE
Terazosab 10 mg comprimés	not available	BE 220062	AMDIPHARM LIMITED	BE
Terazosab 10 mg tabletten	not available	BE 220062	AMDIPHARM LIMITED	BE
HYTRINE 1 mg, comprimé	not available	340 437.6	AMDIPHARM LIMITED	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
HYTRINE 5 mg, comprimé	not available	341 302.7	AMDIPHARM LIMITED	FR
Hytrin 1 mg + 2 mg comprimidos	not available	8683649	AMDIPHARM LIMITED	PT
Hytrinex, 10 mg tabletter	not available	11666	AMDIPHARM LIMITED	SE
Hytrinex, 2 mg tabletter	not available	11046	AMDIPHARM LIMITED	SE
Hytrinex, 5 mg tabletter	not available	11047	AMDIPHARM LIMITED	SE
Sinalfa, 1 mg tabletter	not available	11621	AMDIPHARM LIMITED	SE
HYTRIN 2 mg	not available	58/270/96-B/C	AMDIPHARM LIMITED	CZ
Sinalfa, tabletter	not available	12082	AMDIPHARM LIMITED	DK
Sinalfa, tabletter	not available	12627	AMDIPHARM LIMITED	DK

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
HYTRIN Balení pro zahájení léčby	not available	58/270/96-A/C	AMDIPHARM LIMITED	CZ
TERAFLUSS 5 mg compresse	not available	035046046	ROTTAPHARM S.P.A.	IT
TERAFLUSS 5 mg compresse	not available	035046022	ROTTAPHARM S.P.A.	IT
Magnurol 5 mg comprimidos	not available	60.599	AMDIPHARM LIMITED	ES
Deflox 5 mg comprimidos	not available	60382	AMDIPHARM LIMITED	ES
HYTRIN 5 mg	not available	58/270/96-C/C	AMDIPHARM LIMITED	CZ
Hytrin 1 mg Tabletten	not available	1739/93062492	AMDIPHARM LIMITED	LU
Hytrin 2 mg Tabletten	not available	1739/93062493	AMDIPHARM LIMITED	LU
Hytrin 5 mg Tabletten	not available	1739/93062494	AMDIPHARM LIMITED	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
Hytrin 10 mg Tabletten	not available	1739/93062495	AMDIPHARM LIMITED	LU
Terazosab 1 mg Tabletten	not available	1739/00110033	AMDIPHARM LIMITED	LU
Terazosab 2 mg Tabletten	not available	1739/00110034	AMDIPHARM LIMITED	LU
Terazosab 5 mg Tabletten	not available	1739/00110035	AMDIPHARM LIMITED	LU
Terazosab 10 mg Tabletten	not available	1739/00110036	AMDIPHARM LIMITED	LU
Hytrin 1 mg comprimés	not available	1739/93062492	AMDIPHARM LIMITED	LU
Hytrin 2 mg comprimés	not available	1739/93062493	AMDIPHARM LIMITED	LU
Hytrin 5 mg comprimés	not available	1739/93062494	AMDIPHARM LIMITED	LU
Hytrin 10 mg comprimés	not available	1739/93062495	AMDIPHARM LIMITED	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
Terazosab 1 mg comprimés	not available	1739/00110033	AMDIPHARM LIMITED	LU
Terazosab 2 mg comprimés	not available	1739/00110034	AMDIPHARM LIMITED	LU
Terazosab 5 mg comprimés	not available	1739/00110035	AMDIPHARM LIMITED	LU
Terazosab 10 mg comprimés	not available	1739/00110036	AMDIPHARM LIMITED	LU
TERAFLUSS 2 mg compresse	not available	035046034	ROTTAPHARM S.P.A.	IT
HYTRIN 2 mg	not available	58/0295/18-S	AMDIPHARM LIMITED	SK
HYTRIN 5 mg	not available	58/0296/18-S	AMDIPHARM LIMITED	SK
HYTRIN 10 mg	not available	58/0297/18-S	AMDIPHARM LIMITED	SK
HYTRIN Balenie na začatie liečby	not available	58/0581/97-S	AMDIPHARM LIMITED	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
Sinalfa, tabletter	not available	12626	AMDIPHARM LIMITED	DK
Terazosin 5 mg Tablets	not available	PL 20072/0030	AMDIPHARM UK LIMITED	UK
Hytrin 5 mg Tablets	not available	PL 20072/0030	AMDIPHARM UK LIMITED	UK
Heitrin® 2 mg Tabletten	not available	4912.01.00	AMDIPHARM LIMITED	DE
Heitrin® 5 mg Tabletten	not available	4912.02.00	AMDIPHARM LIMITED	DE
Heitrin® 1 mg Tabletten	not available	4912.00.00	AMDIPHARM LIMITED	DE
DYSALFA 1 mg, comprimé	not available	342 429-0	AMDIPHARM LIMITED	FR
DYSALFA 5 mg, comprimé	not available	342 431-5	AMDIPHARM LIMITED	FR
DYSALFA 1 mg, comprimé Chlorhydrate de térazosine dihydraté	not available	342 430-9	AMDIPHARM LIMITED	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
DYSALFA 5 mg, comprimé Chlorhydrate de térazosine dihydraté	not available	342 432-1	AMDIPHARM LIMITED	FR
Sinalfa	not available	8259	AMDIPHARM LIMITED	NO
Sinalfa	not available	97-244	AMDIPHARM LIMITED	NO
Hytrin, 10 mg, tabletki	not available	7680	AMDIPHARM LIMITED	PL
Hytrin, 2 mg, tabletki	not available	7678	AMDIPHARM LIMITED	PL
Hytrin, 5 mg, tabletki	not available	7679	AMDIPHARM LIMITED	PL
Sinalfa	not available	97-242	AMDIPHARM LIMITED	NO
Sinalfa	not available	97-243	AMDIPHARM LIMITED	NO
Terazosin 1 mg Tablets	not available	PL 20072/0028	AMDIPHARM UK LIMITED	UK

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
Hytrin 1 mg Tablets	not available	PL 20072/0028	AMDIPHARM UK LIMITED	UK
TERAPROST 5 mg compresse	not available	028651026	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
TERAPROST 2 mg compresse	not available	028651014	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
TERAPROST 10 mg compresse	not available	028651053	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
Hytrin startverpakking, tabletten	not available	RVG 16646	AMDIPHARM LIMITED	NL
Hytrin startverpakking, tabletten	not available	RVG 16646	AMDIPHARM LIMITED	NL
Terazosin 2 mg Tablets	not available	PL 20072/0029	AMDIPHARM UK LIMITED	UK
Terazosin 10 mg Tablets	not available	PL 20072/0031	AMDIPHARM UK LIMITED	UK
Hytrin 2 mg Tablets	not available	PL 20072/0029	AMDIPHARM UK LIMITED	UK

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
Hytrin 10 mg Tablets	not available	PL 20072/0031	AMDIPHARM UK LIMITED	UK
Vicard 1 mg-Tabletten	not available	1-18683	AMDIPHARM LIMITED	AT
Uroflo 1 mg-Tabletten	not available	1-20343	AMDIPHARM LIMITED	AT
Hytrin 1 mg tabletta	not available	OGYI-T-4842/01	AMDIPHARM LIMITED	HU
Hytrin 2 mg tabletta	not available	OGYI-T-4842/02	AMDIPHARM LIMITED	HU
Hytrin 5 mg tabletta	not available	OGYI-T-4842/03	AMDIPHARM LIMITED	HU
Hytrin	not available	RVG 14559	AMDIPHARM LIMITED	NL
Hytrin	not available	RVG 14560	AMDIPHARM LIMITED	NL
Hytrin 10, tabletten 10 mg	not available	RVG 14561	AMDIPHARM LIMITED	NL

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
Hytrin 5 mg comprimidos	not available	8683656	AMDIPHARM LIMITED	PT
Hytrinex, 1 mg tabletter	not available	11045	AMDIPHARM LIMITED	SE
Sinalfa, 10 mg tabletter	not available	11691	AMDIPHARM LIMITED	SE
Sinalfa, 2 mg tabletter	not available	11622	AMDIPHARM LIMITED	SE
Sinalfa, 5 mg tabletter	not available	11623	AMDIPHARM LIMITED	SE