



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 July 2024
EMA/545639/2024
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): terazosin

Procedure no.: PSUSA/00002895/202311



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 2 mg tabletter	not available	8259	AMDIPHARM LIMITED	NO
Heitrin® 5 mg Tabletten	not available	4912.02.00	AMDIPHARM LIMITED	DE
Terazosab 5 mg Tabletten	not available	BE 220053	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
Hytrin, 10 mg, tabletki	not available	7680	AMDIPHARM LIMITED	PL
Hytrin 5 mg comprimidos	not available	8683656	AMDIPHARM LIMITED	PT
Uroflo 2 mg-Tabletten	not available	1-20342	AMDIPHARM LIMITED	AT
Hytrin 1 mg Tabletten	not available	1739/93062492	AMDIPHARM LIMITED	LU
Hytrin 1 mg comprimés	not available	1739/93062492	AMDIPHARM LIMITED	LU
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
Sinalfa, 10 mg tabletter	not available	11691	AMDIPHARM LIMITED	SE
TERAFLUSS 2 mg compresse	not available	035046034	ROTTAPHARM S.P.A.	IT
HYTRINE 1 mg, comprimé	not available	34009 340 476 1 9	AMDIPHARM LIMITED	FR
HYTRINE 1 mg, comprimé	not available	34009 330 110 4 8	AMDIPHARM LIMITED	FR
HYTRINE 1 mg, comprimé	not available	34009 340 437 6 5	AMDIPHARM LIMITED	FR
Sinalfa 1 mg tabletter	not available	97-242	AMDIPHARM LIMITED	NO
Sinalfa, 1 mg tabletter	not available	11621	AMDIPHARM LIMITED	SE
Sinalfa, 5 mg tabletter	not available	11623	AMDIPHARM LIMITED	SE
Terazosin 2 mg Tablets	not available	PL 20072/0029	AMDIPHARM UK LIMITED	XI
Hytrin 2 mg Tablets	not available	PL 20072/0029	AMDIPHARM UK LIMITED	XI
Terazosab 1 mg Tabletten	not available	BE 220035	AMDIPHARM LIMITED	BE
Terazosab 1 mg comprimés	not available	BE 220035	AMDIPHARM LIMITED	BE
Terazosab 1 mg tabletten	not available	BE 220035	AMDIPHARM LIMITED	BE
TERAFLUSS 5 mg compresse	not available	035046046	ROTTAPHARM 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
TERAFLUSS 5 mg compresse	not available	035046022	ROTTAPHARM S.P.A.	IT
Hytrin 10 mg Tabletten	not available	1739/93062495	AMDIPHARM LIMITED	LU
Hytrin 10 mg comprimés	not available	1739/93062495	AMDIPHARM LIMITED	LU
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
Hytrin 2 mg Tabletten	not available	BE138101	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
Hytrin, 5 mg, tabletki	not available	7679	AMDIPHARM LIMITED	PL
Heitrin® 1 mg Tabletten	not available	4912.00.00	AMDIPHARM LIMITED	DE
Terazosab 1 mg Tabletten	not available	2000110033	AMDIPHARM LIMITED	LU
Terazosab 1 mg comprimés	not available	2000110033	AMDIPHARM LIMITED	LU
Terazosab 10 mg Tabletten	not available	BE 220062	AMDIPHARM LIMITED	BE
Terazosab 10 mg tabletten	not available	BE 220062	AMDIPHARM LIMITED	BE
Terazosab 10 mg comprimés	not available	BE 220062	AMDIPHARM LIMITED	BE
Hytrin 10 mg Tabletten	not available	BE138031	AMDIPHARM LIMITED	BE
Hytrin 10 mg comprimés	not available	BE 138031	AMDIPHARM LIMITED	BE
Hytrin 10 mg tabletten	not available	BE138031	AMDIPHARM LIMITED	BE
Heitrin® 5 mg Tabletten	not available	4912.02.00	AMDIPHARM LIMITED	DE
Vicard 5 mg-Tabletten	not available	1-18684	AMDIPHARM LIMITED	AT
Hytrin 10, tabletten 10 mg	not available	RVG 14561	AMDIPHARM LIMITED	NL
Terazosab 2 mg Tabletten	not available	BE 220044	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
TERAPROST 5 mg compresse	not available	028651026	MALESCI ISTITUTO FARMACOBIOLOGICO - 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
TERAPROST 2 mg compresse	not available	028651014	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
Hytrin 1mg and 2mg Tablets (Starter Pack)	not available	PA 1142/5/1	AMDIPHARM LIMITED	IE
Hytrin 2 mg Tabletten	not available	1739/93062493	AMDIPHARM LIMITED	LU
Hytrin 2 mg comprimés	not available	1739/93062493	AMDIPHARM LIMITED	LU
Vicard 1 mg-Tabletten	not available	1-18683	AMDIPHARM LIMITED	AT
Hytrin 5 mg δισκίο	not available	48962/09/22-4-2010	AMDIPHARM LIMITED	GR
Sinalfa 10 mg tabletter	not available	97-244	AMDIPHARM LIMITED	NO
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
Terazosab 1 mg Tabletten	not available	BE 220035	AMDIPHARM LIMITED	BE
Terazosab 1 mg comprimés	not available	BE 220035	AMDIPHARM LIMITED	BE
Terazosab 1 mg tabletten	not available	BE 220035	AMDIPHARM LIMITED	BE
Sinalfa	not available	12626	AMDIPHARM LIMITED	DK
Vicard 2 mg-Tabletten	not available	1-18685	AMDIPHARM LIMITED	AT
Hytrin 5 mg tabletten	not available	BE 138092	AMDIPHARM LIMITED	BE
Hytrin 5 mg comprimés	not available	BE 138092	AMDIPHARM LIMITED	BE
Hytrin 5 mg Tabletten	not available	BE138092	AMDIPHARM LIMITED	BE
Magnurol 5 mg comprimidos	not available	60.599	AMDIPHARM LIMITED	ES
DYSALFA 1 mg, comprimé	not available	34009 342 429 0 8	AMDIPHARM LIMITED	FR
DYSALFA 1 mg, comprimé	not available	34009 342 430 9 7	AMDIPHARM LIMITED	FR
Hytrin 2 mg δισκίο	not available	48960/09/22-4-2010	AMDIPHARM LIMITED	GR
Hytrin 5 mg Tabletten	not available	1739/93062494	AMDIPHARM LIMITED	LU
Hytrin 5 mg comprimés	not available	1739/93062494	AMDIPHARM LIMITED	LU
Sinalfa, 2 mg tabletter	not available	11622	AMDIPHARM LIMITED	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
Heitrin® 2 mg Tabletten	not available	4912.01.00	AMDIPHARM LIMITED	DE
Hytrin 5 mg tabletten	not available	BE 138092	AMDIPHARM LIMITED	BE
Hytrin 5 mg comprimés	not available	BE 138092	AMDIPHARM LIMITED	BE
Hytrin 5 mg Tabletten	not available	BE138092	AMDIPHARM LIMITED	BE
Hytrin 5 mg Tablets	not available	PA 1142/5/3	AMDIPHARM LIMITED	IE
Sinalfa 5 mg tabletter	not available	97-243	AMDIPHARM LIMITED	NO
Hytrin 10 mg Tablets	not available	PA 1142/5/4	AMDIPHARM LIMITED	IE
Sinalfa	not available	12082	AMDIPHARM LIMITED	DK
Terazosab 2 mg Tabletten	not available	2000110034	AMDIPHARM LIMITED	LU
Terazosab 2 mg comprimés	not available	2000110034	AMDIPHARM LIMITED	LU
Terazosab 10 mg Tabletten	not available	2000110036	AMDIPHARM LIMITED	LU
Terazosab 10 mg comprimés	not available	2000110036	AMDIPHARM LIMITED	LU
UNOPROST 5 mg compresse	not available	028652028	LABORATORI GUIDOTTI S.P.A.	IT
UNOPROST 2 mg compresse	not available	028652016	LABORATORI GUIDOTTI S.P.A.	IT
URODIE 2,5 mg/ml Gocce Orali, Soluzione	not available	028284040	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
Uroflo 5 mg-Tabletten	not available	1-20341	AMDIPHARM LIMITED	AT
Heitrin® 1 mg Tabletten	not available	4912.00.00	AMDIPHARM LIMITED	DE
Hytrin 5, tabletten 5 mg	not available	RVG 14560	AMDIPHARM LIMITED	NL
Terazosin 5 mg Tablets	not available	PL 20072/0030	AMDIPHARM UK LIMITED	XI
Hytrin 5 mg Tablets	not available	PL 20072/0030	AMDIPHARM UK LIMITED	XI
Hytrin 1 mg + 2 mg comprimidos	not available	8683649	AMDIPHARM LIMITED	PT
Terazosin 1 mg Tablets	not available	PL 20072/0028	AMDIPHARM UK LIMITED	XI
Hytrin 1 mg Tablets	not available	PL 20072/0028	AMDIPHARM UK LIMITED	XI
Hytrin 1 mg Tabletten	not available	BE 138047	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
Deflox 5 mg comprimidos	not available	60382	AMDIPHARM LIMITED	ES

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
HYTRINE 5 mg, comprimé	not available	341 302.7	AMDIPHARM LIMITED	FR
Hytrin 2, tabletten 2 mg	not available	RVG 14559	AMDIPHARM LIMITED	NL
Terazosab 5 mg Tabletten	not available	2000110035	AMDIPHARM LIMITED	LU
Terazosab 5 mg comprimés	not available	2000110035	AMDIPHARM LIMITED	LU
Uroflo 1 mg-Tabletten	not available	1-20343	AMDIPHARM LIMITED	AT
Hytrin, 2 mg, tabletki	not available	7678	AMDIPHARM LIMITED	PL
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
Heitrin® 2 mg Tabletten	not available	4912.01.00	AMDIPHARM LIMITED	DE
DYSALFA 5 mg comprime	not available	342 431-5	AMDIPHARM LIMITED	FR
DYSALFA 5 mg, comprimé Chlorhydrate de térazosine dihydraté	not available	342 432-1	AMDIPHARM LIMITED	FR
ITRIN 5 mg compresse	not available	026929036	S.F. GROUP SRL	IT
ITRIN 2 mg compresse	not available	026929024	S.F. GROUP SRL	IT
Terazosin 10 mg Tablets	not available	PL 20072/0031	AMDIPHARM UK LIMITED	XI
Hytrin 10 mg Tablets	not available	PL 20072/0031	AMDIPHARM UK LIMITED	XI
Hytrin 2 mg Tablets	not available	PA 1142/5/2	AMDIPHARM LIMITED	IE
Sinalfa	not available	12627	AMDIPHARM LIMITED	DK