



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 July 2016
EMA/437334/2016
Procedure Management and Committees Support Division

List of nationally authorised medicinal products

Active substance: Terazosin

Procedure no.: PSUSA/00002895/201511



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
Flotrin Max		29390.02.00	Mibe Gmbh Arzneimittel	Germany
Flotrin Pro		29390.00.00	Mibe Gmbh Arzneimittel	Germany
Flotrin Start		29390.03.00	Mibe Gmbh Arzneimittel	Germany
Flotrin Uro		29390.01.00	Mibe Gmbh Arzneimittel	Germany
Hytrin		58/270/96-A/C & 58/270/96-B/C & 58/270/96-C/C	Amdipharm Limited	Czech Republic
Hytrin		OGYI-T-4842/01 & OGYI-T-4842/02 & OGYI-T-4842/03	Amdipharm Limited	Hungary
Itrin		026929024 & 026929036	Ecupharma S.R.L.	Italy
Terafluss		035046022 & 035046034 & 035046046	Rottapharm S.P.A.	Italy
Teraprost		028651014 & 028651026 & 028651053*	Malesci Istituto Farmacobiologico - S.P.A.	Italy
Unoprost		028652016 & 028652028 & 028652081*	Laboratori Guidotti S.P.A.	Italy
Uro-Hytrin		BE 204154 & BE 204163 & BE 204172 & BE 204181	Amdipharm Limited	Belgium
Uro-Hytrin Starter Pack		BE 204197	Amdipharm Limited	Belgium
Urodie		028284014	Laboratorio Farmaceutico S.I.T. S.R.L.	Italy
Urodie		028284026	Laboratorio Farmaceutico S.I.T. S.R.L.	Italy
Urodie		028284040*	Laboratorio Farmaceutico S.I.T. S.R.L.	Italy
Urodie		028284053	Laboratorio Farmaceutico S.I.T. S.R.L.	Italy
Hytrinex		11045 ^a & 11047 ^a & 11666 ^b	Amdipharm Limited	Sweden
Sinalfa		11621 ^a & 11622 ^a & 11623 ^a & 11691 ^b	Amdipharm Limited	Sweden

URO-HYTRIN 2 mg /comprimés		1739/00010002	Amdipharm Limited	Luxembourg
URO-HYTRIN 1 mg /comprimés		1739/00010001	Amdipharm Limited	Luxembourg
URO-HYTRIN 5 mg /comprimés		1739/00010003	Amdipharm Limited	Luxembourg
URO-HYTRIN 10 mg /comprimés		1739/00010004	Amdipharm Limited	Luxembourg
URO-HYTRIN Starter pack 1 + 2 mg comprimés		1739/00010005	Amdipharm Limited	Luxembourg
TERAZOSAB 1mg comprimés		1739/00110033	Amdipharm Limited	Luxembourg
TERAZOSAB 2mg comprimés		1739/00110034	Amdipharm Limited	Luxembourg
TERAZOSAB 5mg comprimés		1739/00110035	Amdipharm Limited	Luxembourg
TERAZOSAB 10mg comprimés		1739/00110036	Amdipharm Limited	Luxembourg
Hytrin 1mg comprimés		1739/93062492	Amdipharm Limited	Luxembourg
Hytrin 2mg comprimés		1739/93062493	Amdipharm Limited	Luxembourg
Hytrin 5mg comprimés		1739/93062494	Amdipharm Limited	Luxembourg
Hytrin 10mg comprimés		1739/93062495	Amdipharm Limited	Luxembourg
Magnurol 2 mg tablet		60.598	Amdipharm Limited	Spain
Magnurol 5 mg tablet		60.599	Amdipharm Limited	Spain
HYTRIN		RVG 14558	Amdipharm Limited	Netherlands
HYTRIN 1 mg + 2 mg starter pack		RVG 16646	Amdipharm Limited	Netherlands
HYTRIN 5 mg		88303/13-12-2011	Amdipharm Limited	Greece
HYTRIN starter pack		12158/14-10-2015.	Amdipharm Limited	Greece
HYTRINE 2 mg		330-111-0-30 tabs	Amdipharm Limited	France
HYTRIN 2 mg		58/0581/97-S	Amdipharm Limited	Slovakia
TERAZOSIN Starter Pack		58/0581/97-S	Amdipharm Limited	Slovakia
HYTRIN 10mg		58/0581/97-S	Amdipharm Limited	Slovakia
DEFLOX 2mg		60381	Amdipharm Limited	Spain
DEFLOX 5mg		60382	Amdipharm Limited	Spain

HYTRIN 5mg		S00416	Amdipharm Limited	Cyprus
HYTRIN 1 mg comprimidos		8683607, 1/46/85	Amdipharm Limited	Portugal
SINALFA		12626	Amdipharm Limited	Denmark
Hytrin 1mg Tablets		MA 625/00101	Amdipharm Limited	Malta
Hytrin 2mg Tablets		MA 625/00102	Amdipharm Limited	Malta
Hytrin 5mg Tablets		MA 625/00103	Amdipharm Limited	Malta
Hytrin 10mg Tablets		MA 625/00104	Amdipharm Limited	Malta
HYTRIN 2 mg		88311/13-12-2011	Amdipharm Limited	Greece
HYTRIN 2 mg comprimidos		8683615, 1/46/85	Amdipharm Limited	Portugal
HYTRIN 10 mg comprimidos		8683631, 1/46/85	Amdipharm Limited	Portugal
HYTRINE 10 mg		330 113-3-30 tabs	Amdipharm Limited	France
HYTRIN 5 mg comprimidos		8683656, 1/46/85	Amdipharm Limited	Portugal
Hytrin BPH 10mg Tablets		PL 20072/0035	Amdipharm Limited	United Kingdom
Hytrin BPH 1mg Tablets		PL 20072/0032	Amdipharm Limited	United Kingdom
Hytrin BPH 2mg Tablets		PL 20072/0033	Amdipharm Limited	United Kingdom
Hytrin BPH 5mg Tablets		PL 20072/0034	Amdipharm Limited	United Kingdom
Hytrin Tablets 10mg		PL 20072/0031	Amdipharm Limited	United Kingdom
Hytrin Tablets 1mg		PL 20072/0028	Amdipharm Limited	United Kingdom
Hytrin Tablets 2mg		PL 20072/0029	Amdipharm Limited	United Kingdom
Hytrin Tablets 5mg		PL 20072/0030	Amdipharm Limited	United Kingdom
DYSALFA 5 mg comprime		342 431-5 - 28 tabs & 342 432-1-30 tabs	Amdipharm Limited	France
DYSALFA 1 mg comprime		342 429-0-15 tabs & 3420430-9-28 tabs	Amdipharm Limited	France
HYTRINE 5 mg		330 112-7-30 tabs & 341 302-7-28 tabs	Amdipharm Limited	France
Vicard 1 mg-Tabletten		1-18683	Amdipharm Limited	Austria
HYTRIN		RVG 14559 & RVG 14560 & RVG 14561	Amdipharm Limited	Netherlands

HYTRIN		BE 138031 ^a & BE 138047 ^a & BE 138092 ^b & BE 138101 ^b	Amdipharm Limited	Belgium
HYTRINE 1 mg		330 110-4-30 tabs & 340 476.1-28 tabs & 340 437.6-15 tabs	Amdipharm Limited	France
Sinalfa 2 mg tabletter		8259	Amdipharm Limited	Norway
Hytrin tablets 2 mg		7678	Amdipharm Limited	Poland
Hytrin tablets 5 mg		7679	Amdipharm Limited	Poland
Hytrin tablets 10 mg		7680	Amdipharm Limited	Poland
HYTRIN 5 mg		58/0581/97-S	Amdipharm Limited	Slovakia
Vicard 5 mg-Tabletten		1-18684	Amdipharm Limited	Austria
Vicard 2 mg-Tabletten		1-18685	Amdipharm Limited	Austria
Uroflo 5 mg-Tabletten		1-20341	Amdipharm Limited	Austria
TERAZOSAB		BE 220035 & BE 220044	Amdipharm Limited	Belgium
Hytrinex 2 mg tabletter		11046	Amdipharm Limited	Sweden
Uroflo 2 mg-Tabletten		1-20342	Amdipharm Limited	Austria
SINALFA		12082	Amdipharm Limited	Denmark
Heitrin® 1 mg Tabletten		4912.00.00	Amdipharm Limited	Germany
Uroflo 1 mg-Tabletten		1-20343	Amdipharm Limited	Austria
Heitrin® 2 mg Tabletten		4912.01.00	Amdipharm Limited	Germany
TERAZOSAB		BE 220053 & BE 220062	Amdipharm Limited	Belgium
Heitrin® 5 mg Tabletten		4912.02.00	Amdipharm Limited	Germany
HYTRIN Tablets 1mg		PA 1142/5/1	Amdipharm Limited	Ireland
HYTRIN Tablets 2mg		PA 1142/5/2	Amdipharm Limited	Ireland

HYTRIN Tablets 5mg		PA 1142/5/3	Amdipharm Limited	Ireland
HYTRIN Tablets 10mg		PA 1142/5/4	Amdipharm Limited	Ireland
SINALFA		12627	Amdipharm Limited	Denmark
HYTRIN 5 mg comprimidos		8683623, 1/46/85	Amdipharm Limited	Portugal
HYTRIN 1 mg + 2 mg comprimidos		8683649, 1/46/85	Amdipharm Limited	Portugal
Sinalfa startpack (1 mg + 2 mg) tabletter		97-242	Amdipharm Limited	Norway
Sinalfa 10 mg tabletter		97-244	Amdipharm Limited	Norway
Sinalfa 5 mg tabletter		97-243	Amdipharm Limited	Norway