



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2015
EMA/398898/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: miconazole / hydrocortisone, miconazole nitrate /
miconazole nitrate, zinc oxide

Procedure no.: PSUSA/00002052/201410



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
Brentacort 20 mg/g miconazolnitrát + 10 mg/g hydrocortison creme		2810-06888-75	Janssen-Cilag A/S - DK	Denmark
Brentacort 20 mg/g miconazolnitrát + 10 mg/g hydrocortison salve		2810-12188-85	Janssen-Cilag A/S - DK	Denmark
Brentan Crema		52664	Distriquímica S.A.	Spain
Daktacort 2% / 1% w/w Cream		PA 748/26/1	Janssen-Cilag Limited - GB	Ireland
Daktacort 2% / 1% w/w cream		PL 00242/0042	Janssen-Cilag Limited - GB	United Kingdom
DAKTACORT 20 mg/g / 10 mg/g cream		20000855	Johnson & Johnson, Prodaja medicinskih in farmacevtskih izdelkov, d.o.o. - SI	Bulgaria
Daktacort crème miconazolnitraat/hydrocortison 20 mg/g / 10 mg/g, crème		RVG 07342	Janssen-Cilag BV - NL	Netherlands
Daktacort zalf miconazolnitraat/hydrocortison 20 mg/g / 10 mg/g, zalf		RVG 11506	Janssen-Cilag BV - NL	Netherlands
Daktacort, Crème		41599	Janssen-Cilag AG - CH	Liechtenstein
Daktacort™ Cream		7082	Janssen-Cilag International NV - BE	Cyprus
Daktacort™ Cream		018/00701	Janssen-Cilag International NV - BE	Malta
Daktacort™ Ointment		PL 00242/0130	Janssen-Cilag Limited - GB	United Kingdom
Daktarin		02806	McNeil Products Limited C/O Johnson & Johnson Limited	Poland

Daktarin		07798	McNeil Products Limited C/O Johnson & Johnson Limited	Poland
Daktarin		08503	McNeil Products Limited C/O Johnson & Johnson Limited	Poland
Daktarin - oral, 20 mg/g, żel do stosowania w jamie ustnej		R/6771	Janssen-Cilag International NV - BE	Poland
DAKTARIN 0,2% soluzione vaginale		024957250	Janssen-Cilag SpA - IT	Italy
DAKTARIN 100 mg ovuli vaginali		024957211	Janssen-Cilag SpA - IT	Italy
DAKTARIN 1200 mg capsule molli vaginali		024957173	Janssen-Cilag SpA - IT	Italy
DAKTARIN 2 POUR CENT, gel buccal		326 806-8	JANSSEN-CILAG - FR	France
DAKTARIN 2 POUR CENT, gel buccal		348 308-0	JANSSEN-CILAG - FR	France
DAKTARIN 2 POUR CENT, poudre pour application locale		319 410-5	JANSSEN-CILAG - FR	France
DAKTARIN 2% - orales Gel		17.956	Janssen-Cilag Pharma GmbH - AT	Austria
Daktarin 2% crema vaginale		024957247	Janssen-Cilag SpA - IT	Italy
DAKTARIN 2% gel orale		024957060	Janssen-Cilag SpA - IT	Italy
DAKTARIN 20 mg/g gel oral		0162/021169501	Janssen-Cilag NV - BE	Luxembourg
DAKTARIN 20 mg/g gel voor oraal gebruik		BE 108087	Janssen-Cilag NV - BE	Belgium
Daktarin 20 mg/g valgomasis gelis		LT/1/97/2125/002	UAB Johnson & Johnson - LT	Lithuania
Daktarin 20 mg/g valgomasis gelis		LT/1/97/2125/001	UAB Johnson & Johnson - LT	Lithuania

DAKTARIN 400 mg capsule molli vaginali		024957312	Janssen-Cilag SpA - IT	Italy
Daktarin Cream		PL 00242/0016	Janssen-Cilag Limited - GB	United Kingdom
Daktarin Crema		50271	Laboratorios Dr.Esteve, S.A.	Spain
DAKTARIN DERMATOLOGICO 2% crema		041411024	Janssen-Cilag SpA - IT	Italy
DAKTARIN DERMATOLOGICO 2% polvere cutanea, 1 barattolo da 30 g		041411012	Janssen-Cilag SpA - IT	Italy
DAKTARIN DERMATOLOGICO 2% soluzione cutanea		041411036	Janssen-Cilag SpA - IT	Italy
DAKTARIN DERMATOLOGICO 2% spray cutaneo, polvere		041411048	Janssen-Cilag SpA - IT	Italy
Daktarin Gel Oral		55962	Laboratorios Dr.Esteve, S.A.	Spain
Daktarin gel voor oraal gebruik 20 mg/g, gel		RVG 07490	Janssen-Cilag BV - NL	Netherlands
Daktarin Mundgel		43494	Janssen-Cilag AG - CH	Liechtenstein
DAKTARIN Oral Gel		7225	Janssen-Cilag International NV - BE	Cyprus
DAKTARIN Oral Gel		PL 0242/0048	Janssen-Cilag Limited - GB	United Kingdom
Daktarin Polvo		50272	Laboratorios Dr.Esteve, S.A.	Spain
Daktarin Powder		018/00801	Janssen-Cilag International NV - BE	Malta
DAKTARIN, 20 mg/g suukaudne geel		174697	UAB Johnson & Johnson - LT	Estonia
Daktarin™ Cream		6136	Janssen-Cilag International NV - BE	Cyprus

Daktarin™ Cream.		018/00803	Janssen-Cilag International NV - BE	Malta
DAKTARIN™ Oral Gel		018/00802	Janssen-Cilag International NV - BE	Malta
Daktarin™ Powder		6137	Janssen-Cilag International NV - BE	Cyprus
Engelhard Arzneimittel		44570.00.00 44570.00.01	Mykoderm Mund-Gel Mykoderm Miconazolcreme	Germany
GYNO DAKTARIN 400 mg, capsule molle vaginale		34009 323 871 3 7	JANSSEN- CILAG - FR	France
Gyno-Daktarin 1200 mg capsule voor vaginaal gebruik		RVG 10634	Janssen-Cilag BV - NL	Netherlands
GYNO-DAKTARIN 1200 mg capsules molles vaginales		0162/07049257	Janssen-Cilag NV - BE	Luxembourg
GYNO-DAKTARIN 1200 mg capsules voor vaginaal gebruik, zacht		BE 133034	Janssen-Cilag NV - BE	Belgium
Gyno-Daktarin 1200 mg vaginal capsule		PA 748/20/2	Janssen-Cilag Limited - GB	Ireland
Gyno-Daktarin 1200 mg vaginal capsule		PL 0242/0121	Janssen-Cilag Limited - GB	United Kingdom
GYNO-DAKTARIN 20 mg/g crème vaginale		0162/07045255	Janssen-Cilag NV - BE	Luxembourg
GYNO-DAKTARIN 20 mg/g crème voor vaginaal gebruik		BE 000987	Janssen-Cilag NV - BE	Belgium
Gyno-Daktarin 20 mg/g vaginal cream		6138	Janssen-Cilag International NV - BE	Cyprus
Gyno-Daktarin 20 mg/g vaginal cream		PA 748/20/1	Janssen-Cilag Limited - GB	Ireland
Gyno-Daktarin 20 mg/g vaginal cream		018/00805	Janssen-Cilag International NV - BE	Malta
Gyno-Daktarin 20 mg/g, crème voor vaginaal gebruik		RVG 06221	Janssen-Cilag BV - NL	Netherlands

GYNO-DAKTARIN 200 mg capsules molles vaginales		0162/07049256	Janssen-Cilag NV - BE	Luxembourg
GYNO-DAKTARIN 200 mg capsules voor vaginaal gebruik, zacht		BE 108771	Janssen-Cilag NV - BE	Belgium
Gyno-Daktarin 20mg/g cream		PL 0242/0015	Janssen-Cilag Limited - GB	United Kingdom
GYNO-DAKTARIN 400 capsules for vaginal use		018/00806	Janssen-Cilag International NV - BE	Malta
Gyno-Daktarin 400 mg capsules for vaginal use		9658	Janssen-Cilag International NV - BE	Cyprus
Gyno-Daktarin 400 mg capsules voor vaginaal gebruik		RVG 10633	Janssen-Cilag BV - NL	Netherlands
GYNO-DAKTARIN 400 mg capsules voor vaginaal gebruik, zacht		BE 112892	Janssen-Cilag NV - BE	Belgium
GYNO-DAKTARIN Κολπική κρέμα 2%		54882	Janssen-Cilag Pharmaceutical S.A.C.I. - GR	Greece
GYNO-DAKTARIN Κολπικό υπόθετο 200 MG/SUP		1360	Janssen-Cilag Pharmaceutical S.A.C.I. - GR	Greece
GYNO-DAKTARIN Κολπικό υπόθετο 400 MG/SUP		1361	Janssen-Cilag Pharmaceutical S.A.C.I. - GR	Greece
Gyno-Femidazol		02813	Gedeon Richter Polska Sp. z o.o.	Poland
InfectoSoor Zinksalbe		27617.00.00	InfectoPharm Arzneimittel und Consilium GmbH	Germany
LORAMYC 50 mg, muco-achhesive buccal tablet	FR/H/0329/001	NL 32125	ONXEO (formelly BioAlliance Pharma)	France
LORAMYC 50 mg, muco-achhesive buccal tablet	FR/H/0329/001	70864.00.00	ONXEO (formelly	Germany

			BioAlliance Pharma)	
LORAMYC 50 mg, muco-achhesive buccal tablet	FR/H/0329/001	038371011	ONXEO (formelly BioAlliance Pharma)	Italy
LORAMYC 50 mg, muco-achhesive buccal tablet	FR/H/0329/001	PL 31030/0001	ONXEO (formelly BioAlliance Pharma)	United Kingdom
Miconal		22198	Tarchomińskie Zakłady Farmaceutyczne "Polfa" S.A.	Poland
Miconal		09501	Tarchomińskie Zakłady Farmaceutyczne "Polfa" S.A.	Poland
Miconazolnitraat J-C vaginale crème 20 mg/g		RVG 20639=06221	Janssen-Cilag BV - NL	Netherlands
Miconazolnitraat/hydrocortison crème J-C 20 mg/g / 10 mg/g		RVG 20600=07342	Janssen-Cilag BV - NL	Netherlands
MICOTEF 0.2% soluzione vaginale		023491160	Teofarma S.R.L.	Italy
MICOTEF 2% crema cutanea		023491172	Teofarma S.R.L.	Italy
MICOTEF 2% gel orale		023491133	Teofarma S.R.L.	Italy
Monistat		37065	Janssen-Cilag AG - CH	Liechtenstein
Monistat Ovula		38222	Janssen-Cilag AG - CH	Liechtenstein
NIZACOL 500 mg tablets		025999121	New Research s.r.l.	Italy
PRILAGIN (dermatologico) – crema dermatologico		025904020	Sofar S.p.A	Italy
PRILAGIN (dermatologico) – latte dermatologico		025904018	Sofar S.p.A	Italy
PRILAGIN (ginecologico) – capsule vaginali da 1200mg		025901057	Sofar S.p.A	Italy

PRILAGIN (ginecologico) – capsule vaginali da 1200mg		025904069	Sofar S.p.A	Italy
PRILAGIN (ginecologico) – capsule vaginali da 400mg		025904044	Sofar S.p.A	Italy
PRILAGIN (ginecologico) – crema ginecologica		025904069	Sofar S.p.A	Italy
PRILAGIN (ginecologico) – soluzione vaginale		025904032	Sofar S.p.A	Italy
TIBOZOLE 10 mg buccale tabletten		BE233877	Janssen R&D Ireland - IE	Belgium