



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 October 2016
EMA/805214/2016
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: dexamethasone (apart from centrally authorised products)

Procedure no.: PSUSA/00000973/201601



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
Aacidexam		2008079848	Aspen Pharma Trading Limited	Luxembourg
Aacidexam		BE 080026	Aspen Pharma Trading Limited	Belgium
Decadron		014729038	Farmaceutici Caber S.P.A.	Italy
Decadron		014729077 \$ 014729089 \$ 014729127 \$ 014729139	Farmaceutici Caber S.P.A.	Italy
Decadron		014729141	Farmaceutici Caber S.P.A.	Italy
Decadron		3546587 \$ 3546686	Laboratório Medinfar - Produtos Farmacêuticos, S.A.	Portugal
Dectancyl		302 853-6	Sanofi-Aventis France	France
Dermadex		022500019	Teofarma S.R.L.	Italy
Dexa Loscon Mono		6709922.00.00	Galderma Laboratorium Gmbh	Germany
Dexa-Effekton		6239244.00.00	Teofarma S.R.L.	Germany
Dexa-Ophtal Sine		91156.00.00	Dr. Gerhard Mann Chem.-Pharm. Fabrik Gmbh	Germany
Dexa-Sine		12339.00.00	Alcon Pharma Gmbh	Germany
Dexa-Sine Se		6863959.00.00	Alcon Pharma Gmbh	Germany
Dexafluid	DE/H/2715/001/DC	80767.00.00	Mibe Gmbh Arzneimittel	Germany
Dexafluid	DE/H/5049/001/DC	HR-H-788697780	Mibe Pharmaceuticals D.O.O.	Croatia
Dexafluid Sine	DE/H/5049/001/DC	92373.00.00	Mibe Gmbh Arzneimittel	Germany
Dexamethason Acis		93932.00.00	Acis Arzneimittel Gmbh	Germany
Dexamethason Bipharma	HU/H/0384/001	RVG 116172	Bipharma B.V.	Netherlands
Dexamethason Teva		RVG 29754	Teva Nederland B.V.	Netherlands
Dexamethasone		PL 39699/0060	Aspen Pharma Trading Limited	United Kingdom
Dexamethasone		PA 1691/014/001	Aspen Pharma Trading Limited	Ireland
Dexamethasone		PL 39699/0056	Aspen Pharma Trading Limited	United Kingdom
Dexamethasone		PL 17507/0052	Auden Mckenzie (Pharma Division) Ltd	United Kingdom

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Dexamethasone Bipharma	HU/H/0384/001	OGYI-T-22917/01 \$ OGYI-T-22917/02 \$ OGYI-T-22917/03 \$ OGYI-T-22917/04 \$ OGYI-T-22917/05	Bipharma B.V.	Hungary
Dexamethasone Bipharma	HU/H/0384/01	BE489662	Bipharma B.V.	Belgium
Dexamethasone		PL 04515/0019	Hospira Uk Ltd	United Kingdom
Dexamethasone		PL 04515/0020	Hospira Uk Ltd	United Kingdom
Dexamethasone		PL 20620/0092 \$ PL 20620/0093 \$ PL 20620/0094 \$ PL 20620/0095 \$ PL 20620/0096 \$ PL 20620/0097	Lime Pharma Ltd	United Kingdom
Dexamethasone Phosphate	UK/H/5450/001/DC	PA 1887/001/001	Alissa Healthcare Research Limited	Ireland
Dexamethasone Phosphate	UK/H/5450/001/DC	PL 30322/0001	Alissa Healthcare Research Limited	United Kingdom
Dexamethasone		PA 437/14/02	Hospira Uk Ltd	Ireland
Dexamethasone Sodium Phosphate	UK/H/5556/01/DC	PA1339/052/001	Wockhardt Uk Ltd	Ireland
Dexamethasone Sodium Phosphate	UK/H/5556/01/DC	29831/0589	Wockhardt Uk Ltd	United Kingdom
Dropodex	MT/H/0157/001/DC	MA 999/00101	Moorfields Eye Hospital Nhs Foundation Trust	Malta
Dropodex	MT/H/0157/001/DC	PA1464/003/001	Moorfields Eye Hospital Nhs Foundation Trust	Ireland
Dropodex	MT/H/0157/001/DC	PL 11412/0145	Moorfields Eye Hospital Nhs Foundation Trust	United Kingdom
Etacortilen		018805022	S.I.F.I. S.P.A.	Italy
Etacortilen		018805034	S.I.F.I. S.P.A.	Italy
Etacortilen		018805046	S.I.F.I. S.P.A.	Italy
Fortecortin		1-17215	Merck Gesellschaft Mbh	Austria
Fortecortin		1-17216	Merck Gesellschaft Mbh	Austria
Fortecortin		1-18431	Merck Gesellschaft Mbh	Austria
Fortecortin		1-18432	Merck Gesellschaft Mbh	Austria
Fortecortin		1-19393	Merck Gesellschaft Mbh	Austria

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Fortecortin		1-19399	Merck Gesellschaft Mbh	Austria
Fortecortin		11.742	Merck Gesellschaft Mbh	Austria
Fortecortin		56/1139/93-C	Merck Kгаа	Czech Republic
Fortecortin		23764.00.00	Merck Serono Gmbh	Germany
Fortecortin		9587.00.00	Merck Serono Gmbh	Germany
Fortecortin		9587.01.00	Merck Serono Gmbh	Germany
Fortecortin		9587.02.00	Merck Serono Gmbh	Germany
Fortecortin Inject		486.00.00	Merck Serono Gmbh	Germany
Fortecortin Inject		486.01.00	Merck Serono Gmbh	Germany
Fortecortin Inject		9739.00.00	Merck Serono Gmbh	Germany
Fortecortin Inject		9739.01.00	Merck Serono Gmbh	Germany
Fortecortin		70032	Merck, S.L.	Spain
Fortecortin		70078	Merck, S.L.	Spain
Fortecortin		E.N.32.224	Merck, S.L.	Spain
Isopto-Dex		15626.00.00	Alcon Pharma Gmbh	Germany
Isopto-Maxidex		07236	Sa Alcon-Couvreur Nv	Sweden
Isopto-Maxidex		5454	Sa Alcon-Couvreur Nv	Norway
Isopto® -Dex		6375533.00.01	Alcon Pharma Gmbh	Germany
Käärmepakkaus		3047	Aspen Pharma Trading Limited	Finland
Lipotalon		8509.00.00	Recordati Pharma Gmbh	Germany
Luxazone		017837016	Allergan S.P.A.	Italy
Luxazone		017837028	Allergan S.P.A.	Italy
Maxidex		17329	A. Potamitis Medicare Ltd	Cyprus
Maxidex		199598	Sa Alcon-Couvreur Nv	Estonia
Maxidex		2005098235	Alcon Nv	Luxembourg
Maxidex		2005098236	Alcon Nv	Luxembourg
Maxidex		4630/2004/01	Sa Alcon-Couvreur Nv	Romania
Maxidex		46847/21-9-2009	Alcon Laboratories Hellas S.A.	Greece
Maxidex		4879	Sa Alcon-Couvreur Nv	Denmark
Maxidex		751900 (IS)	Sa Alcon-Couvreur Nv	Iceland
Maxidex		BE038857	Alcon Nv	Belgium

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Maxidex		BE149895	Alcon Nv	Belgium
Maxidex		H/94/00972/001	Sa Alcon-Couvreur Nv	Slovenia
Maxidex		H/94/00972/002	Sa Alcon-Couvreur Nv	Slovenia
Maxidex		HR-H-085077338	Alcon Farmaceutika D.O.O.	Croatia
Maxidex		HR-H-444452701	Alcon Farmaceutika D.O.O.	Croatia
Maxidex		LT/1/92/0003/001	Sa Alcon-Couvreur Nv	Lithuania
Maxidex		LT/1/92/0003/002	Sa Alcon-Couvreur Nv	Lithuania
Maxidex		015/01002	Sa Alcon-Couvreur Nv	Malta
Maxidex		OGYI-T-6910/01	Alcon Hungarian Ltd.	Hungary
Maxidex		PA 290/56/1	Alcon Laboratories (UK) Ltd	Ireland
Maxidex		PA 290/56/2	Alcon Laboratories (UK) Ltd	Ireland
Maxidex		PL 00649/5914R	Alcon Laboratories (UK) Ltd	United Kingdom
Maxidex		3400930652473/VNL 8426	Laboratoires Alcon S.A.S	France
Oftacortal		042016016	Farmigea Spa	Italy
Oftan Dexa		98-0733	Santen Oy	Latvia
Oftan Dexa		LT/1/95/2483/001	Santen Oy	Lithuania
Oftan Dexa		LT/1/95/2483/002	Santen Oy	Lithuania
Oradexon		3974581	Aspen Pharma Trading Limited	Portugal
Oradexon		5890	Aspen Pharma Trading Limited	Finland
Oradexon		8042903	Aspen Pharma Trading Limited	Portugal
Oradexon		RVG 00113 \$ RVG 00114	Aspen Pharma Trading Limited	Netherlands
Oradexon		RVG 56517	Aspen Pharma Trading Limited	Netherlands
Soldesam		019499	Laboratorio Farmacologico Milanese	Italy
Soldesanil		21265/2-4-2008	Diapit Dimitrios P Diamantis	Greece
Soldesanil		21266/2-4-2008	Diapit Dimitrios P Diamantis	Greece
Soldesanil		21267/2-4-2008	Diapit Dimitrios P Diamantis	Greece
Solupen Sine		54573.00.00	Dr. Winzer Pharma Gmbh	Germany
Spersadex		6308991.00.00	Omnivision Gmbh	Germany

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Thilodexine		43897/07/12-6-2008	Pharmex S.A.	Greece
Thilodexine		43900/07/12-6-2008	Pharmex S.A.	Greece
Thilodexine		43901/07/12-6-2008	Pharmex S.A.	Greece
Tuttozem N		6380847.00.00	Strathmann Gmbh & Co. Kg	Germany
Usoldec		042541019 \$ 042541021	Genetic Spa	Italy
Visumetazone		015980016	Visufarma Spa	Italy
максидекс		9600003	Alcon Bulgaria Eood	Bulgaria
максидекс		9600041	Alcon Bulgaria Eood	Bulgaria
Fortecortin		E.N. 36.225	Merck, S.L.	Spain
Fortecortin		57036	Merck, S.L.	Spain
Fortecortin Inject		1979110556	Merck Serono Gmbh	Luxembourg
Fortecortin Inject		1979110557	Merck Serono Gmbh	Luxembourg
Fortecortin Inject		2000016330	Merck Serono Gmbh	Luxembourg
Fortecortin Inject		2000016331	Merck Serono Gmbh	Luxembourg
Fortecortin		1983090769	Merck Serono Gmbh	Luxembourg
Fortecortin		1997024283	Merck Serono Gmbh	Luxembourg
Fortecortin		1997070475	Merck Serono Gmbh	Luxembourg
Dexagel		6249975.00.00	Dr. Gerhard Mann Chem.- Pharm. Fabrik Gmbh	Germany
Dexa EDO		6249998.00.00	Dr. Gerhard Mann Chem.- Pharm. Fabrik Gmbh	Germany
Dexa-Rhinospray N sine		54573.01.00	Dr. Gerhard Mann Chem.- Pharm. Fabrik Gmbh	Germany
Dexa-Ophtal		6024816.00.00	Dr. Winzer Pharma Gmbh	Germany
Decadron		14729014	Farmaceutici Caber S.P.A.	Italy
Dexamethasone	UK/H/4489/01/DC	31741/10-6-2014	Rosemont Pharmaceuticals	Greece
Dexamethasone	UK/H/4489/01/DC	MT 48703	Rosemont Pharmaceuticals	Sweden