



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 September 2021
EMA/709165/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: dexamethasone (apart from centrally authorised products)

Procedure no.: PSUSA/00000973/202101

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



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
Fortecortin 100 mg – Ampulle	not available	1-17216	MERCK GESELLSCHAFT MBH	AT
Fortecortin 4 mg – Ampullen	not available	11.742	MERCK GESELLSCHAFT MBH	AT
Fortecortin 40 mg – Ampulle	not available	1-17215	MERCK GESELLSCHAFT MBH	AT
Fortecortin Inject 100 mg - Spritzampulle	not available	1-18432	MERCK GESELLSCHAFT MBH	AT
Fortecortin Inject 40 mg – Spritzampulle	not available	1-18431	MERCK GESELLSCHAFT MBH	AT
Dexamethason NewLine Pharma 1,5 mg/ml Augentropfen, Lösung	PT/H/2182/001	5782446	NEWLINE PHARMA S.L.	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
Dexamethason NewLine Pharma 1,5 mg/ml Augentropfen, Lösung	PT /H/2182/001	2205593.00.00	NEWLINE PHARMA S.L.	AT
Fortecortin 4 mg – Tabletten	not available	1-19393	MERCK GESELLSCHAFT MBH	AT
Fortecortin 8 mg – Tabletten	not available	1-19399	MERCK GESELLSCHAFT MBH	AT
Dexagel 0,985 mg/g Augengel	DE/H/4097/001	136816	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	AT
MAXIDEX 1 mg/g oogzalf	not available	BE149895	NOVARTIS PHARMA N.V.	BE
MAXIDEX 1 mg/ml oogdruppels, suspensie	not available	BE038857	NOVARTIS PHARMA N.V.	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
MAXIDEX, 1 mg/ml, collyre en suspension	not available	BE038857	NOVARTIS PHARMA N.V.	BE
MAXIDEX 1 mg/g pommade ophtalmique	not available	BE149895	NOVARTIS PHARMA N.V.	BE
MAXIDEX 1 mg/ml Augentropfensuspension	not available	BE038857	NOVARTIS PHARMA N.V.	BE
MAXIDEX 1 mg/g Augensalbe	not available	BE149895	NOVARTIS PHARMA N.V.	BE
Dexamethasone Bipharma 1 mg/ml, oogdruppels, oplossing in verpakking voor éénmalig gebruik	HU/H/0384/001	BE489662	BIPHARMA B.V.	BE
Dexamethasone Bipharma 1 mg/ml collyre en solution en récipient unidose	HU/H/0384/001	BE489662	BIPHARMA B.V.	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
Dexamethasone Bipharma 1 mg/ml Augentropfen, Lösung in einem Einzeldosisbehältnis	HU/H/0384/001	BE489662	BIPHARMA B.V.	BE
AACIDEXAM 5 mg/ml oplossing voor injectie	not available	BE 080026	ASPEN PHARMA TRADING LIMITED	BE
AACIDEXAM 5 mg/ml solution injectable	not available	BE 080026	ASPEN PHARMA TRADING LIMITED	BE
Aacidexam 5 mg/ml Injektionslösung Dexamethasondihydroge nphosphat-Dinatrium	not available	BE 080026	ASPEN PHARMA TRADING LIMITED	BE
МАКСИДЕКС 1 mg/ml капки за очи, суспензия	not available	9600003	NOVARTIS PHARMA GMBH	BG
ORATORIA 1 mg/ml οφθαλμικές σταγόνες, διάλυμα	DK/H/2733/001	023179	PHARMATHEN S.A.	CY

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
Dexamethasone sodium phosphate New Line Pharma 1,5 mg/ml ορρρα.Α.μ1Κτι; ρrmy6w:i;, οul.Α.υμα.	PT/H/2182/001	023181	NEWLINE PHARMA S.L.	CY
Dexamethasone/RAFARM [PF]	PT/H/2365/001	023006	RAFARM SA.	CY
Maxidex 0,1% w/v Οφθαλμικές σταγόνες, εναιώρημα	not available	17329	NOVARTIS IRELAND LIMITED	CY
Fortecortin 4 mg tablety	not available	56/1139/93-C	MERCK SPOL.S.R.O.	CZ
Dexamethason acis® 0,76 mg/ml Augentropfen Wirkstoff: Dexamethasondihydrogenphosphat-Dinatrium	not available	93932.00.00	ACIS ARZNEIMITTEL GMBH	DE

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
Dexamethason NTC 1 mg/ml Augentropfen, Lösung im Einzeldosisbehältnis	PT/H/2041/001	2202073.00.00	NTC SRL	DE
Dexa-Ophtal® 1,32 mg/ml Augentropfen, Lösung	not available	6024816.00.00	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	DE
Dexa-Sine® 1 mg/ml Augentropfen	not available	12339.00.00	IMMEDICA PHARMA AB	DE
Oratoria1 mg/ml Augentropfen, Lösung	DK/H/2733/001	99362.00.00	PHARMATHEN S.A.	DE
Spersadex Augentropfen, Lösung	not available	6308991.00.00	OMNIVISION GMBH	DE

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
Fortecortin® 0,5 mg Tabletten	not available	9587.00.00	MERCK SERONO GMBH	DE
Fortecortin® 2 mg Tabletten	not available	9587.01.00	MERCK SERONO GMBH	DE
Fortecortin® 4 mg Tabletten	not available	23764.00.00	MERCK SERONO GMBH	DE
Fortecortin® 8 mg Tabletten	not available	9587.02.00	MERCK SERONO GMBH	DE
DEXA-SINE® SE 1,315 mg/ml Augentropfen	not available	6863959.00.00	IMMEDICA PHARMA AB	DE
Fortecortin® Inject 40 mg Injektionslösung in einer Ampulle	not available	486.00.00	MERCK SERONO GMBH	DE

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
Fortecortin® Inject 100 mg Injektionslösung in einer Fertigspritze	not available	486.01.00	MERCK SERONO GMBH	DE
Fortecortin® Inject 4 mg Injektionslösung in einer Ampulle	not available	9739.00.00	MERCK SERONO GMBH	DE
Fortecortin® Inject 8 mg Injektionslösung in einer Ampulle	not available	9739.01.00	MERCK SERONO GMBH	DE
Fortecortin® Inject 100 mg Injektionslösung in einer Ampulle	not available	486.01.00	MERCK SERONO GMBH	DE
Fortecortin® Inject 40 mg Injektionslösung in einer Fertigspritze	not available	486.00.00	MERCK SERONO GMBH	DE
Dexa EDO® 1,3 mg/ml Augentropfen, Lösung	not available	6249998.00.00	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	DE

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
Dexagel® 0,985 mg/g, viskosierte Augentropfen	not available	6249975.00.00	DR. GERHARD MANN CHEM.- PHARM. FABRIK GMBH	DE
ISOPTO®-DEX 1 mg/ml Augentropfensuspension Wirkstoff: Dexamethason	not available	15626.00.00	NOVARTIS PHARMA GMBH	DE
Dexafluid® 1 mg/ml Augentropfen	DE/H/2715/001	80767.00.00	MIBE GMBH ARZNEIMITTEL	DE
Solupen® sine 0,15 mg/g Nasenspray, Lösung	not available	54573.00.00	DR. GERHARD MANN CHEM.- PHARM. FABRIK GMBH	DE
Dexa-Ophtal sine 1,3 mg/ml Augentropfen, Lösung	not available	91156.00.00	DR. GERHARD MANN CHEM.- PHARM. FABRIK GMBH	DE

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
Lipotalon* 4 mg, Emulsion zur Injektion Wirkstoff: Dexamethason-21-palmitat	not available	8509.00.00	RECORDATI PHARMA GMBH	DE
Dexa-Rhinospray® N sine, 0,15 mg/g Nasenspray, Lösung	not available	54573.01.00	DR. GERHARD MANN CHEM.- PHARM. FABRIK GMBH	DE
Dexagel 0,985 mg/g Augengel	DE/H/4097/001	91848.00.00	DR. GERHARD MANN CHEM.- PHARM. FABRIK GMBH	DE
Dexafluid sine 1,315 mg/ml Augentropfen im Einzeldosisbehältnis	DE/H/5049/001/DC	92373.00.00	MIBE GMBH ARZNEIMITTEL	DE
Maxidex, øjendråber, suspension	not available	4879	NOVARTIS HEALTHCARE A/S	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
Oratoria 1 mg/ml øjendråber, opløsning	DK/H/2733/001	58913	PHARMATHEN S.A.	DK
Maxidex 1 mg/ml silmatilgad, suspensioon	not available	199598	SIA NOVARTIS BALTICS	EE
Dexagel 0,985 mg/g silimageel	DE/H/4097/001	906616	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	EE
Dexametasona NTC 1 mg/ml colirio en solución en envase unidosis	PT/H/2041/001	84712	NTC SRL	ES
Fridex 1 mg/ml colirio en solución	ES/H/0745/001	85484	NTC SRL	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
Dexametasona Kern Pharma 7,2 mg solución inyectable	not available	85.636	KERN PHARMA, S.L.	ES
Fortecortín 4 mg comprimidos	not available	70032	LABORATORIOS ERN, S.A.	ES
Fortecortín 8 mg comprimidos	not available	70078	LABORATORIOS ERN, S.A.	ES
Dexametasona sodio fosfato NewLine Pharma 1,5 mg/ml colirio en solución	PT/H/2182/001	84548	NEWLIN PHARMA S.L.	ES
Fortecortín 4 mg/ml solución inyectable	not available	36.225	LABORATORIOS ERN, S.A.	ES
Fortecortín 40 mg/5 ml solución inyectable	not available	57.036	LABORATORIOS ERN, S.A.	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
Dexametasona POS 1 mg/ml colirio en solución	not available	84559	BRILL PHARMA, S.L.	ES
Fortecortín 1 mg comprimidos	not available	32.224	LABORATORIOS ERN, S.A.	ES
Oradexon 5 mg/ml injektioneste, liuos	not available	5890	ASPEN PHARMA TRADING LIMITED	FI
Oradexon 5 mg/ml injektionsvätska, lösning	not available	5890	ASPEN PHARMA TRADING LIMITED	FI
DEXOCOL 1 mg/mL, collyre en solution	DK/H/2733/001	34009 301 797 3 4	HORUS PHARMA	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
DEXOCOL 1 mg/mL, collyre en solution	DK/H/2733/001	34009 301 797 4 1	HORUS PHARMA	FR
MAXIDEX 0,1 POUR CENT, collyre	not available	34009 306 524 7 3	NOVARTIS PHARMA S.A.S.	FR
MAXIDEX 0,1 POUR CENT, collyre	not available	34009 355 851 8 9	NOVARTIS PHARMA S.A.S.	FR
DEXAMETHASONE NEWLINE PHARMA 1,5 mg/mL, collyre en solution	PT/H/2182/001	NL49417	NEWLINE PHARMA S.L.	FR
DEXAMETHASONE PANPHARMA 20 mg/5 mL, solution injectable	PT/H/1666/002	34009 550 771 5 2	PANPHARMA	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
DEXAMETHASONE PANPHARMA 20 mg/5 mL, solution injectable	PT/H/1666/002	34009 550 771 6 9	PANPHARMA	FR
MAXIDEX 0,1 POUR CENT, collyre	not available	34009 306 524 7 3	NOVARTIS PHARMA S.A.S.	FR
MAXIDEX 0,1 POUR CENT, collyre	not available	34009 355 851 8 9	NOVARTIS PHARMA S.A.S.	FR
DEXAMETHASONE/RAFA RM 1mg/ml, collyre en solution [PF]	UK/H/6954/001	6 083 355 9	RAFARM SA.	FR
DECTANCYL 0,5 MG, COMPRIME	not available	34009 302 853 6 7	SANOFI-AVENTIS FRANCE	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
ORATORIA 1 mg/ml οφθαλμικές σταγόνες, διάλυμα	DK/H/2733/001	98910/16/04-07-2018	PHARMATHEN S.A.	GR
REXAZON 4 mg Διαλυτά δισκία	not available	45793/10-05-2018	RAFARM SA.	GR
REXAZON 8 mg Διαλυτά δισκία	not available	45794/10-05-2018	RAFARM SA.	GR
SOLDESANIL 2 mg/ml πόσιμες σταγόνες, διάλυμα	not available	0132102	DIAPIT S.A.	GR
Maxidex 0,1% w/v Οφθαλμικές σταγόνες, εναίωρημα	not available	003700101	NOVARTIS (HELLAS) S.A.C.I.	GR

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
SOLDESANIL 4 mg/1 ML AMP ενέσιμο διάλυμα	not available	0132101	DIAPIT S.A.	GR
DEXAMETHASONE/ROSE MONT 10 mg/5 ml Πόσιμο Διάλυμα	UK/H/0709/001	55453/17/17-01-2019	RAFARM SA.	GR
Dexamethasone sodium phosphate NewLine Pharma 1,5 mg/ml οφθαλμικές σταγόνες, διάλυμα	PT/H/2182/001	20403	NEWLIN PHARMA S.L.	GR
Dexamethasone/RAFARM [PF]	UK/H/6954/001	30318/28-03-2019	RAFARM SA.	GR
MAXIDEX 1 mg/g mast za oko	not available	HR-H-444452701-01	NOVARTIS HRVATSKA D.O.O.	HR

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
MAXIDEX 1 mg/ml kapi za oko, suspenzija	not available	HR-H-085077338-01	NOVARTIS HRVATSKA D.O.O.	HR
Dexagel 0,985 mg/g gel za oko	DE/H/4097/001	HR-H-386811844	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	HR
Maxidex 1 mg/ml szuszpenziós szemcsepp	not available	OGYI-T-6910/01	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Dexamethasone Bipharma 1 mg/ml oldatos szemcsepp egyadagos tartályban	HU/H/0384/001	OGYI-T-22917/01	BIPHARMA B.V.	HU
Dexamethasone Bipharma 1 mg/ml oldatos szemcsepp egyadagos tartályban	HU/H/0384/001	OGYI-T-22917/02	BIPHARMA B.V.	HU

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
Dexamethasone Bipharma 1 mg/ml oldatos szemcsepp egyadagos tartályban	HU/H/0384/001	OGYI-T-22917/03	BIPHARMA B.V.	HU
Dexamethasone Bipharma 1 mg/ml oldatos szemcsepp egyadagos tartályban	HU/H/0384/001	OGYI-T-22917/04	BIPHARMA B.V.	HU
Dexamethasone Bipharma 1 mg/ml oldatos szemcsepp egyadagos tartályban	HU/H/0384/001	OGYI-T-22917/05	BIPHARMA B.V.	HU
Dexamethasone Phosphate 4 mg/ml Solution for Injection	not available	PA 0822/201/001	PFIZER HEALTHCARE IRELAND	IE
Dexamethasone phosphate NewLine Pharma 1.37 mg/ml eye drops, solution in single dose container	PT/H/2182/001	PA2115/002/001	NEWLINE PHARMA S.L.	IE

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
Dexamethasone 2mg Tablets	not available	PA 1691/014/001	ASPEN PHARMA TRADING LIMITED	IE
Maxidex 0.1% w/v Eye Drops, Suspension	not available	PA 0896/018/001	NOVARTIS IRELAND LIMITED	IE
Maxidex, 1 mg/ml augndropar, dreifa	not available	751900	NOVARTIS HEALTHCARE A/S	IS
OFTACORTAL 0,15% collirio, soluzione	not available	042016016	FARMIGEA SPA	IT
USOLDEC 0,15% collirio, soluzione	not available	042514021	GENETIC SPA	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
USOLDEC 0,15% collirio, soluzione	not available	042514019	GENETIC SPA	IT
Luxazone 2 mg/ml collirio, sospensione	not available	017837028	ALLERGAN S.P.A.	IT
Luxazone 2 mg/g unguento oftalmico	not available	017837016	ALLERGAN S.P.A.	IT
SOLDESAM 0,2% gocce orali, soluzione	not available	019499072	LABORATORIO FARMACOLOGICO MILANESE S.R.L.	IT
SOLDESAM 0,2% GOCCE ORALI, SOLUZIONE	not available	019499096	LABORATORIO FARMACOLOGICO MILANESE S.R.L.	IT
SOLDESAM 4 mg/1 ml soluzione iniettabile	not available	019499019	LABORATORIO FARMACOLOGICO MILANESE 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
SOLDESAM 8 mg/2 ml soluzione iniettabile	not available	019499084	LABORATORIO FARMACOLOGICO MILANESE S.R.L.	IT
Fridex 1 mg/ml collirio, soluzione	ES/H/0745/001	048806018	NTC SRL	IT
DESADOC 1,5 mg/ml collirio, soluzione	not available	045264013	DOC GENERICI S.R.L.	IT
Dexavision 1 mg/mL collirio, soluzione	DK/H/2733/001	045535010	FB VISION SRL	IT
Dexavision 1 mg/mL collirio, soluzione	DK/H/2733/001	045535022	FB VISION SRL	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
VISUMETAZONE 1mg/ml Collirio, sospensione	not available	015980016	VISUFARMA SPA	IT
Varcodes 2 mg compresse effervescenti	not available	045136013	EPIONPHARMA S.R.L.	IT
Varcodes 4 mg compresse effervescenti	not available	045136025	EPIONPHARMA S.R.L.	IT
Varcodes 8 mg compresse effervescenti	not available	045136037	EPIONPHARMA S.R.L.	IT
USOLDEC 0,15% collirio, soluzione	not available	042514021	GENETIC SPA	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
USOLDEC 0,15% collirio, soluzione	not available	042514019	GENETIC SPA	IT
Decadron 0,5 MG Comprese 10 compresse	not available	014729014	I.B.N. SAVIO S.R.L.	IT
Decadron 2 mg/ml gocce orali, soluzione	not available	014729141	I.B.N. SAVIO S.R.L.	IT
Decadron 0,5 MG Comprese -30 compresse	not available	014729178	I.B.N. SAVIO S.R.L.	IT
Decadron "8 mg/2 ml Soluzione iniettabile"	not available	014729089	I.B.N. SAVIO S.R.L.	IT
Decadron "4 mg/1 ml Soluzione iniettabile"	not available	014729077	I.B.N. SAVIO 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
Decadron "8 mg/2 ml Soluzione iniettabile"	not available	014729139	I.B.N. SAVIO S.R.L.	IT
Decadron "4 mg/1 ml Soluzione iniettabile"	not available	014729127	I.B.N. SAVIO S.R.L.	IT
Decadron 2 mg/ml gocce orali, soluzione	not available	014729154	I.B.N. SAVIO S.R.L.	IT
Decadron 0,5 MG Compresse 20 compresse	not available	014729166	I.B.N. SAVIO S.R.L.	IT
Decadron 0,75 MG Compresse 20 compresse	not available	014729180	I.B.N. SAVIO S.R.L.	IT
Decadron 0,75 MG Compresse -30 compresse	not available	014729192	I.B.N. SAVIO 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
Decadron 0,75 MG Comprese 10 compresse	not available	014729038	I.B.N. SAVIO S.R.L.	IT
Decadron "8 mg/2 ml Soluzione iniettabile"	not available	014729216	I.B.N. SAVIO S.R.L.	IT
Decadron "4 mg/1 ml Soluzione iniettabile"	not available	014729204	I.B.N. SAVIO S.R.L.	IT
Etacortilen 1,5 mg/ml gel oftalmico	not available	018805046	SIFI S.P.A.	IT
Dermadex	not available	022500019	TEOFARMA S.R.L.	IT
Decadron 0,5 MG Comprese 10 compresse	not available	014729014	I.B.N. SAVIO 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
Decadron 2 mg/ml gocce orali, soluzione	not available	014729141	I.B.N. SAVIO S.R.L.	IT
Decadron 0,5 MG Compresse -30 compresse	not available	014729178	I.B.N. SAVIO S.R.L.	IT
Decadron "8 mg/2 ml Soluzione iniettabile"	not available	014729089	I.B.N. SAVIO S.R.L.	IT
Decadron "4 mg/1 ml Soluzione iniettabile"	not available	014729077	I.B.N. SAVIO S.R.L.	IT
Decadron "8 mg/2 ml Soluzione iniettabile"	not available	014729139	I.B.N. SAVIO S.R.L.	IT
Decadron "4 mg/1 ml Soluzione iniettabile"	not available	014729127	I.B.N. SAVIO 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
Decadron 2 mg/ml gocce orali, soluzione	not available	014729154	I.B.N. SAVIO S.R.L.	IT
Decadron 0,5 MG Compresse 20 compresse	not available	014729166	I.B.N. SAVIO S.R.L.	IT
Decadron 0,75 MG Compresse 20 compresse	not available	014729180	I.B.N. SAVIO S.R.L.	IT
Decadron 0,75 MG Compresse -30 compresse	not available	014729192	I.B.N. SAVIO S.R.L.	IT
Decadron 0,75 MG Compresse 10 compresse	not available	014729038	I.B.N. SAVIO S.R.L.	IT
Decadron "8 mg/2 ml Soluzione iniettabile"	not available	014729216	I.B.N. SAVIO 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
Decadron "4 mg/1 ml Soluzione iniettabile"	not available	014729204	I.B.N. SAVIO S.R.L.	IT
Etacortilen 1,5 mg/ml collirio, soluzione	not available	018805034	SIFI S.P.A.	IT
Etacortilen 1,5 mg/ml collirio, soluzione	not available	018805022	SIFI S.P.A.	IT
SURFEDEX 1 mg/ml, collirio, soluzione .	UK/H/6954/001/DC	047636016	BRUSCHETTINI S.R.L	IT
Maxidex 1 mg/g akių tepalas	not available	LT/1/92/0003/001	SIA "NOVARTIS BALTICS"	LT
Maxidex 1 mg/ml akių lašai (suspensija)	not available	LT/1/92/0003/002	SIA NOVARTIS BALTICS	LT

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
OFTAN DEXA 1 mg/ml akių lašai (tirpalas)	not available	LT/1/95/2483/001	SANTEN OY	LT
OFTAN DEXA 1 mg/ml akių lašai (tirpalas)	not available	LT/1/95/2483/002	SANTEN OY	LT
DEXAL 0,985 mg/g akių gelis	DE/H/4097/001	LT/1/16/3968/001	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LT
Spersadex Augentropfen, Lösung	not available	1978060250	OMNIVISION GMBH	LU
Fortecortin® Inject 4 mg Injektionslösung in einer Ampulle	not available	46142	MERCK SERONO GMBH	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
Fortecortin® Inject 8 mg Injektionslösung in einer Ampulle	not available	46187	MERCK SERONO GMBH	LU
Fortecortin® Inject 100 mg Injektionslösung in einer Fertigspritze	not available	46139	MERCK SERONO GMBH	LU
Fortecortin® Inject 40 mg Injektionslösung in einer Fertigspritze	not available	46173	MERCK SERONO GMBH	LU
Fortecortin® 4 mg Tabletten	not available	197411	MERCK SERONO GMBH	LU
Fortecortin® 8 mg Tabletten	not available	235041	MERCK SERONO GMBH	LU
Fortecortin® 8 mg Tabletten	not available	235038	MERCK SERONO GMBH	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
Fortecortin® 0,5 mg Tabletten	not available	197391	MERCK SERONO GMBH	LU
Fortecortin® 4 mg Tabletten	not available	46125	MERCK SERONO GMBH	LU
Fortecortin® 8 mg Tabletten	not available	235055	MERCK SERONO GMBH	LU
Aacidexam 5 mg/ml Injektionslösung Dexamethasondihydrogenphosphat-Dinatrium	not available	2008079848	ASPEN PHARMA TRADING LIMITED	LU
AACIDEXAM 5 mg/ml solution injectable	not available	2008079848	ASPEN PHARMA TRADING LIMITED	LU
OFTAN DEXA 1 mg/ml acu pilieni, šķīdums	not available	98-0733	SANTEN OY	LV

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
Dexagel 0,985 mg/g acu gels	DE/H/4097/001	16-0113	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LV
Dropodex 0.1% w/v Eye Drops, solution.	MT/H/0157/001	MA 1182/00101	RAYNER PHARMACEUTICALS	MT
MAXIDEX* 1 mg/ml eye drops, suspension	not available	MA1249/01101	NOVARTIS IRELAND LIMITED	MT
Dexamethason Bipharma 1 mg/ml, oogdruppels, oplossing in verpakking voor éénmalig gebruik	HU/H/0384/001	RVG 116172	BIPHARMA B.V.	NL
Dexamethason Teva 4 mg, tabletten	not available	RVG 29754	TEVA NEDERLAND B.V.	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
Oradexon 5 mg/ml, oplossing voor injectie	not available	RVG 56517	ASPEN PHARMA TRADING LIMITED	NL
Dexamethason Newline Pharma 1,5 mg/ml oogdruppels, oplossing	PT/H/2360/001/E/001	RVG 126062	NEWLIN PHARMA S.L.	NL
Isopto-Maxidex 1 mg/ml øyedråper, suspensjon	not available	5454	NOVARTIS NORGE AS	NO
Dexaprotect, 1 mg/ml, krople do oczu, roztwór	DK/H/2733/001	25737	S-LAB SP.ZO.O.	PL
Demezón, 1 mg, tabletki	not available	25034	SUN-FARM SP. Z.O.O.	PL

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
Demezón, 1,315 mg/ml, krople do oczu, roztwór w pojemniku jednodawkowym	DE/H/5049/001	23142	SUN-FARM SP. Z.O.O.	PL
Dexametasona NTC	PT/H/2041/001	5782271	NTC SRL	PT
Oradexon 5 mg/ml Solução injectável	not available	3974581	ASPEN PHARMA TRADING LIMITED	PT
Decadron 0,5 mg comprimidos	not available	3546587	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
Decadron 0,5 mg comprimidos	not available	3546686	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT

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
Dexametasona NewLine Pharma 1,5 mg/ml colírio, solução	PT/H/2182/001	5782446	NEWLINE PHARMA S.L.	PT
Dexametasona NewLine Pharma 1,5 mg/ml colírio, solução	PT/H/2182/001	5782453	NEWLINE PHARMA S.L.	PT
Dexametasona Panpharma 20 mg/5 mL solução injetável	PT/H/1666/002	5806062	PANPHARMA	PT
Dexametasona Panpharma 20 mg/5 mL solução injetável	PT/H/1666/002	5806062	PANPHARMA	PT
Dexavit 1 mg/ml colírio, solução	PT/H/2365/001	5785928	RAFARM SA.	PT

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
MAXIDEX 1mg/ml picături oftalmice suspensie	not available	11112/2018/01	NOVARTIS PHARMA GMBH	RO
Dexametazonă fosfat de sodiu NewLine Pharma 1,5 mg/ml picături oftalmice, soluție	PT/H/2182/001	12709/2019/01	NEWLIN PHARMA S.L.	RO
Dexametazonă fosfat de sodiu NewLine Pharma 1,5 mg/ml picături oftalmice, soluție	PT/H/2182/001	12709/2019/02	NEWLIN PHARMA S.L.	RO
Oratoria 1 mg/ml ögondroppar, lösning	DK/H/2733/001	55868	PHARMATHEN S.A.	SE
ISICORT 4 mg orodispersible film	not available	0	ACUCORT AB	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
ISICORT 6 mg orodispersible film	not available	0	ACUCORT AB	SE
ISICORT 8 mg orodispersible film	not available	0	ACUCORT AB	SE
Baxil 1 mg/ml ögondroppar, lösning i endosbehållare	not available	59167	ORIFARM GENERICS A/S	SE
Isopto-Maxidex 1 mg/ml ögondroppar, suspension	not available	07236	NOVARTIS SVERIGE AB	SE
MAXIDEX 1 mg/g mazilo za oko	not available	H/94/00972/001	NOVARTIS PHARMA GMBH	SI

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
MAXIDEX 1 mg/ml kapljice za oko, suspenzija	not available	H/94/00972/002	NOVARTIS PHARMA GMBH	SI
Dexamethasone 1 mg tablets	UK/H/6788/001	PL 12762/0617	MERCURY PHARMACEUTICALS LTD.	XI
Dexamethasone phosphate 1 mg/mL (as sodium phosphate) Eye drops, Solution in a single-dose container	PT/H/2041/001	PL 35730/0015	NTC SRL	XI
Dexamethasone Tablets BP 2.0mg	not available	PL 39699/0056	ASPEN PHARMA TRADING LIMITED	XI
MAXIDEX 0.1% w/v, eye drops, suspension	not available	PL 00101/0999	NOVARTIS PHARMACEUTICALS UK LIMITED	XI

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
Dropodex 0.1% w/v Eye Drops, solution.	MT/H/0157/001	PL 47069/0003	RAYNER PHARMACEUTICALS	XI
Martapan 2mg/5ml Oral Solution	UK/H/1897/001	PL 00156/0125	MARTINDALE PHARMACEUTICALS LTD	XI
Dexamethasone 3.8 mg/ml solution for injection	not available	PL 39699/0060	ASPEN PHARMA TRADING LIMITED	XI
PURADEX	PT/H/2365/001/IB/002	PL 46130/0001	RAFARM UK LIMITED	XI
Eythalm 1 mg/ml eye drops, solution	DK/H/2733/001	PL35533/0118	ASPIRE PHARMA LIMITED	XI