



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 October 2015
EMA/707111/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: clobetasol

Procedure no.: PSUSA/00000799/201502



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
Butavate		18757/19-3-10 \$ 32522/11-10-07 \$ 66478/11-10-07	Glaxosmithkline Aebe	Greece
Clarelux	UK/H/619/01	1- 26157	Pierre Fabre Dermatologie	Austria
Clarelux	UK/H/619/01	1646/04030140	Pierre Fabre Benelux	Luxembourg
Clarelux	UK/H/619/01	19532	Pierre Fabre Dermatologie	Poland
Clarelux	UK/H/619/01	216 581-1, 216 582-8	Pierre Fabre Dermatologie	France
Clarelux	UK/H/619/01	15085/24-02-2009	Pierre Fabre Hellas / Greece	Greece
Clarelux	UK/H/619/01	46/0659/11-S	Pierre Fabre Dermatologie	Slovakia
Clarelux	UK/H/619/001	46/604/11-C	Pierre Fabre Dermatologie	Czech Republic
Clarelux	UK/H/619/01	5013180, 5013289	Pfdc / Portugal	Portugal
Clarelux	UK/H/619/01	58909.00.00	Pierre Fabre Dermokosmetik	Germany

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Clarelux	UK/H/619/01	66-071	Pierre Fabre Iberica / Spain	Spain
Clarelux	UK/H/619/01	BE291611	Pierre Fabre Benelux	Belgium
Clarelux	UK/H/619/01	PA 1230/1/1	Pierre Fabre Dermatologie	Ireland
Clarelux	UK/H/619/01	PL 20693/0004	Pierre Fabre Dermatologie	United Kingdom
Clarelux	UK/H/619/01	RVG 30096	Pierre Fabre Benelux	Netherlands
Clarelux	UK/H/619/01	18797	Pierre Fabre Medic	Finland
Clarelux	BE/H/136/01/DC	1128/09020031	Pierre Fabre Dermatologie	Luxembourg
Clarelux	BE/H/136/01/DC	70111	Pierre Fabre Iberica / Spain	Spain
Clarelux	BE/H/136/01/DC	BE320406	Pierre Fabre Benelux	Belgium

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Clobaderm	UK/H/3207/001/DC \$ UK/H/3208/001/DC	32011 \$ 32015	Auden Mckenzie (Pharma Division) Ltd	Finland
Clobaderm	UK/H/3207/001/DC \$ UK/H/3208/001/DC	PA 1352/17/001 \$ PA 1352/17/002	Auden Mckenzie (Pharma Division) Ltd	Ireland
Clobaderm	UK/H/3207/001/MR DC \$ UK/H/3208/001/MR DC	50629 \$ 50630	Auden Mckenzie (Pharma Division) Ltd	Sweden
Clobaderm	UK/H/3207/001/DC \$ UK/H/3208/001/ DC	53596 \$ 53597	Auden Mckenzie (Pharma Division) Ltd	Denmark
Clobaderm	UK/H/3207/001/MR DC, UK/H/3208/001/MR DC	MA561/00701 \$ MA561/00702	Auden Mckenzie (Pharma Division) Ltd	Malta
Clobaderm	UK/H/3207/001/MR DC \$ UK/H/3208/001/MR DC	RVG 114753 \$ RVG 114754	Auden Mckenzie (Pharma Division) Ltd	Netherlands
Clobaderm	UK/H/3208/001/DC	043212012 \$ 043212024	Auden Mckenzie (Pharma Division) Ltd	Italy
Clobesol		023639026 \$ 023639040	Glaxosmithkline S.P.A.	Italy
ClobaDerm	UK/H/3208/001/DC	PL 17507/0236	Auden Mckenzie (Pharma Division) Ltd	United Kingdom

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ClobaDerm	UK/H/3207/001/DC	PL 17507/0235	Auden Mckenzie (Pharma Division) Ltd	United Kingdom
Clobetasolo Auden	UK/H/3207/001/DC	043214016 \$ 043214028	Auden Mckenzie (Pharma Division) Ltd	Italy
Clobetasolo Pierre Fabre	BE/H/136/01/DC	038592010/M, 038592022/M	Pierre Fabre Italia S.P.A.	Italy
Clobex	UK/H/0872/001/DC	2007030028	Galderma Benelux B.V.	Luxembourg
Clobex	UK/H/0872/001/DC	NL 32466, CIS 6 972 430 1	Galderma International	France
Clobex	UK/H/0872/001/DC	BE291891	Galderma Benelux B.V.	Belgium
Clobex	UK/H/0872/001/DC	OGYI-T-20383/01 \$ OGYI-T-20383/02 \$ OGYI-T-20383/03	Galderma International	Hungary
Clobex	UK/H/0872/001/DC	21811	Galderma Nordic Ab	Finland
Clobex	UK/H/0872/001/DC	05-3858	Galderma Nordic Ab	Norway

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Clobex	UK/H/0872/001/DC	12795	Galderma Polska Sp. Z O.O.	Poland
Clobex	UK/H/0872/001/DC	1-26814	Galderma International	Austria
Clobex	UK/H/0872/001/DC	23230	Galderma Nordic Ab	Sweden
Clobex	UK/H/0872/001/DC	38796	Galderma Nordic Ab	Denmark
Clobex	UK/H/0872/001/DC	39183/12-6-08	Galderma Hellas S.A.	Greece
Clobex	UK/H/0872/001/DC	46/037/07-C	Galderma International	Czech Republic
Clobex	UK/H/0872/001/DC	46/0514/06-S	Galderma International	Slovakia
Clobex	UK/H/0872/001/DC	64984.00.00	Galderma Laboratorium Gmbh	Germany
Clobex	UK/H/0872/001/DC	68316	Laboratorios Galderma, S.A.	Spain

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Clobex	UK/H/0872/001/DC	IS/1/06/011/01	Galderma Nordic Ab	Iceland
Clobex	UK/H/0872/001/DC	RVG 33440	Galderma Benelux B.V.	Netherlands
Clobisdin Isdin	ES/H/0250/001/DC	79.415	Isdin, S.A.	Spain
Clovate		55.746	Industrial Farmaceutica Cantabria, S.A.	Spain
Decloban		56530	Teofarma S.R.L.	Spain
Dermoval		NL10403 \$ NL12966	Laboratoire Glaxosmithkline S.A.S.	France
Dermovat		10360 \$ 6325 \$ 6326	Glaxosmithkline Pharma A/S	Denmark
Dermovat		6717 \$ 6718 \$ 7200	Glaxosmithkline As	Norway
Dermovat		6717	Glaxosmithkline As	Norway

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Dermovate		6718	Glaxosmithkline As	Norway
Dermovat		7200	Glaxosmithkline As	Norway
Dermovat		7058 \$ 7059 \$ 7203	Glaxosmithkline Oy	Finland
Dermovat		731640 \$ 731641 \$ 782315	Glaxosmithkline Ehf.	Iceland
Dermovat		9143 \$ 9144	Glaxosmithkline Ab	Sweden
Dermovate Scalp Application		9252	Glaxosmithkline Ab	Sweden
Dermovate Losning		9252	Glaxosmithkline Ab	Sweden
Dermovate		00-0250 \$ 98-0124	Glaxosmithkline Latvia Sia	Latvia
Dermovate		15911 \$ 15910 \$ 16784	Glaxosmithkline Pharma GmbH.	Austria

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Dermovate		16801	Glaxo Group Limited	Cyprus
Dermovate		19785	Glaxo Group Limited	Cyprus
Dermovate Cream		16801	Glaxo Group Limited	Cyprus
Dermovate Scalp Application		19785	Glaxo Group Limited	Cyprus
Dermovate Ointment		16802	Glaxo Group Limited	Cyprus
Dermovate		16802	Glaxo Group Limited	Cyprus
Dermovate		214598	Glaxo Group Limited	Estonia
Dermovate		2229/2009/01 \$ 2230/2009/01	Glaxo Wellcome Ltd	Romania
Dermovate		260/11 01 0948 \$ 260/11 07 1214 \$ 260/11 07 1215	Glaxosmithkline Pharmaceuticals Sa	Luxembourg

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Dermovate		BE091883 \$ BE091892 \$ BE115236	Glaxosmithkline Pharmaceuticals Sa	Belgium
Dermovate		LT/1/94/0647/001 \$ LT/1/94/0647/002 \$ LT/1/94/0647/003	Glaxosmithkline Lietuva Uab	Lithuania
Dermovate Cream		MA 167/00601	Glaxo Wellcome Ltd	Malta
Dermovate Ointment		MA 167/00602	Glaxo Wellcome Ltd	Malta
Dermovate Scalp Application		MA 167/00603	Glaxo Wellcome Ltd	Malta
Dermovate		167/00601, 167/00603	Glaxo Wellcome Ltd	Malta
Dermovate		OGYI-T-1329/01 \$ OGYI-T-1329/02 \$ OGYI-T-1329/03	Glaxosmithkline Kft.	Hungary
Dermovate		10949/0025 \$ 10949/0028 \$ 10949/0046	Glaxo Wellcome Ltd	United Kingdom
Dermovate		R/3699	Glaxosmithkline Export Ltd	Poland

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Dermovate		R/0047	Glaxosmithkline Export Ltd	Poland
Dermovate		R/0048	Glaxosmithkline Export Ltd	Poland
Dermovate		RVG 06932 \$ RVG 06933 \$ RVG 07579	Glaxosmithkline B.V.	Netherlands
Dermoxin		6080252.00.01 \$ 6080252.00.02	Glaxosmithkline Gmbh & Co. Kg	Germany
Dermoxinale		6080252.00.00	Glaxosmithkline Gmbh & Co. Kg	Germany
Etrivex	UK/H/0872/001/DC	037769015 \$ 037769027 \$ 037769039	Galderma Italia S.P.A.	Italy
Etrivex	UK/H/0872/001/DC	5019054 \$ 5019062 \$ 5182829	Laboratorios Galderma Sa – Sucursal Em Portugal	Portugal
Etrivex	UK/H/0872/001/DC	PA590/23/1	Galderma (Uk) Limited	Ireland
Etrivex	UK/H/0872/001/DC	PL 10590/0052	Galderma (Uk) Limited	United Kingdom

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Klobetasolpropionat Auden	UK/H/3207/001/MR DC \$ UK/H/3208/001/MR DC	13/9917 \$ 13/9916	Auden Mckenzie (Pharma Division) Ltd	Norway
Olux	UK/H/0619/001	036580013/M, 036580025/M	Sandoz S.P.A.	Italy
Dermovate 0,05% Cream		20030370	Glaxo Group Limited	Bulgaria
Dermovate		20030369	Glaxo Group Limited	Bulgaria
Dermovate		20030370	Glaxo Group Limited	Bulgaria
Dermovate 0,05% Ointment		20030369	Glaxo Group Limited	Bulgaria
Dermovate		1077/5/1 \$ 1077/5/2 \$ 1077/5/3	Glaxosmithkline (Ireland) Limited	Ireland
Clotrimazolum 10 mg GW_GEN		26/0209/91-C/S	GlaxoSmithKline	Slovakia
Clotrimazole 10 mg_GEN		26/0209/91-C/S	GlaxoSmithKline	Slovakia

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Trimovate		10949/0040	Glaxo Wellcome Ltd	United Kingdom
Dermovate Cream		214498	Glaxo Group Limited	Estonia
Dermovate Ointment		214398	Glaxo Group Limited	Estonia
Clarelux	BE/H/136/01/DC	HR-H-552362353	Oktal Pharma d.o.o.	Croatia
Dermovate		46/429/92-C	Glaxo Group Limited	Czech Republic
Dermovate		46/430/92-C	Glaxo Group Limited	Czech Republic
Clarelux	UK/H/0619/001	IS/1/03/045/01	Pierre Fabre Dermatologie	Iceland