



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

30 May 2018  
EMA/474010/2018  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: adapalene / benzoyl peroxide

Procedure no.: PSUSA/00000059/201709



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
Epiduo 0,1% / 2,5% gel	SE/H/0664/001	22970	GALDERMA NORDIC AB	FI
Epiduo 1 mg/g + 25 mg/g gel	SE/H/0664/001	5571179	LABORATORIOS GALDERMA SA – SUCURSAL EM PORTUGAL	PT
Epiduo 1 mg/g + 25 mg/g gel	SE/H/0664/001	5571203	LABORATORIOS GALDERMA SA – SUCURSAL EM PORTUGAL	PT
Epiduo 0,1 % / 2,5 % Gel	SE/H/0664/001	2008040012	GALDERMA BENELUX B.V.	LU
Epiduo 0,1% /2,5% gel	SE/H/0664/001	038261095	GALDERMA ITALIA S.P.A.	IT
Epiduo 0,1% /2,5% gel	SE/H/0664/001	038261107	GALDERMA ITALIA S.P.A.	IT
Epiduo 0,1% /2,5% gel	SE/H/0664/001	038261071	GALDERMA ITALIA S.P.A.	IT
Epiduo 0,1% /2,5% gel	SE/H/0664/001	038261083	GALDERMA ITALIA S.P.A.	IT
EPIDUO 0,1% / 2,5%, gel	SE/H/0664/001	276 110-5 OU 34009 276 110 5 6	GALDERMA INTERNATIONAL	FR
EPIDUO 0,1% / 2,5%, gel	SE/H/0664/001	276 111-1 OU 34009276 111 1 7	GALDERMA INTERNATIONAL	FR
EPIDUO 0,1% / 2,5%, gel	SE/H/0664/001	276 112-8 OU 34009 276 112 8 5	GALDERMA INTERNATIONAL	FR
EPIDUO 0,1% / 2,5%, gel	SE/H/0664/001	276 113-4 OU 34009 276 113 4 6	GALDERMA INTERNATIONAL	FR
Epiduo 0,1% /2,5% gel	SE/H/0664/001	0382611199	GALDERMA ITALIA S.P.A.	IT
Epiduo 0,1%/2,5% γέλη	SE/H/0664/001	18790/23-2-2016	GALDERMA HELLAS S.A.	GR
Epiduo, gel	SE/H/0664/001	40440	GALDERMA NORDIC AB	DK
Epiduo 0,1% / 2,5% hlaup	SE/H/0664/001	IS/1/09/084/01	GALDERMA NORDIC AB	IS
Epiduo 0,1% /2,5% gel	SE/H/0664/001	038261032	GALDERMA ITALIA S.P.A.	IT
Epiduo 0,1% /2,5% gel	SE/H/0664/001	038261057	GALDERMA ITALIA S.P.A.	IT
Epiduo 0,1% /2,5% gel	SE/H/0664/001	038261044	GALDERMA ITALIA S.P.A.	IT
Epiduo 0,1% /2,5% gel	SE/H/0664/001	038261069	GALDERMA ITALIA S.P.A.	IT
Epiduo 0,1 % / 2,5 % gel	SE/H/0664/001	06-4606	GALDERMA NORDIC AB	NO
Epiduo 0.1% / 2.5% gel	SE/H/0664/001	PL 10590/0057	GALDERMA (UK) LIMITED	UK
Epiduo 0,1% / 2,5% Gel	SE/H/0664/001	1-27380	GALDERMA INTERNATIONAL	AT
EPIDUO 0,1%/2,5% Gel	SE/H/0664/001	BE386337	GALDERMA BENELUX B.V.	BE
EPIDUO 0,1%/2,5% Gel	SE/H/0664/001	BE314203	GALDERMA BENELUX B.V.	BE

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EPIDUO 0,1% / 2,5% Gel	SE/H/0664/001	BE314203	GALDERMA BENELUX B.V.	BE
EPIDUO 0,1% / 2,5% Gel	SE/H/0664/001	BE386337	GALDERMA BENELUX B.V.	BE
Epiduo 0,1 % / 2,5 % Gel	SE/H/0664/001	BE314203	GALDERMA BENELUX B.V.	BE
Epiduo 0,1% / 2,5% Gel	SE/H/0664/001	67913.00.00	GALDERMA LABORATORIUM GMBH	DE
Epiduo 0,1 % / 2,5 % Gel	SE/H/0664/001	BE386337	GALDERMA BENELUX B.V.	BE
Epiduo 1 mg/g + 25 mg/g gel	SE/H/0664/001	69.445	LABORATORIOS GALDERMA SA	ES
EPIDUO 0,1% / 2,5%, gel	SE/H/0664/001	392 203-6 OU 34009 392 203 6 9	GALDERMA INTERNATIONAL	FR
Epiduo 0,1 % / 2,5 % geeli	SE/H/0664/001	22970	GALDERMA NORDIC AB	FI
EPIDUO 0,1% / 2,5%, gel	SE/H/0664/001	383 816-9 OU 34009 383 816 9 6	GALDERMA INTERNATIONAL	FR
EPIDUO 0,1% / 2,5%, gel	SE/H/0664/001	383 814-6 OU 34009 383 814 6 7	GALDERMA INTERNATIONAL	FR
EPIDUO 0,1% / 2,5%, gel	SE/H/0664/001	383 815-2 OU 34009 383 815 2 8	GALDERMA INTERNATIONAL	FR
EPIDUO 0,1% / 2,5%, gel	SE/H/0664/001	383 817-5 OU 34009 383 817 5 7	GALDERMA INTERNATIONAL	FR
Epiduo 0,1% /2,5% gel	SE/H/0664/001	038261020	GALDERMA ITALIA S.P.A.	IT
Epiduo 1 mg/g + 25 mg/g gel	SE/H/0664/001	5078951	LABORATORIOS GALDERMA SA – SUCURSAL EM PORTUGAL	PT
EPIDUO 0,1%/2,5% Gel	SE/H/0664/001	2008040012	GALDERMA BENELUX B.V.	LU
Epiduo 0,1% / 2,5% gel	SE/H/0664/001	24864	GALDERMA NORDIC AB	SE
Tactuo 0,1 % / 2,5% gel	SE/H/0618/001	24865	GALDERMA NORDIC AB	SE
Tactuoben 1 mg/g + 25 mg/g gel	SE/H/0618/001	69446	LABORATORIOS GALDERMA SA	ES

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Epiduo 0,1% + 2,5% zel	SE/H/0664/001	14534	GALDERMA POLSKA SP. Z O.O.	PL
Epiduo 1 mg/g + 25 mg/g gel	SE/H/0664/001	5078969	LABORATORIOS GALDERMA SA – SUCURSAL EM PORTUGAL	PT
Epiduo 1 mg/25 mg/g gels	SE/H/0664/001	LT/1/17/4074/001	GALDERMA INTERNATIONAL	LT
Epiduo 1 mg/25 mg/g gels	SE/H/0664/001	LT/1/17/4074/002	GALDERMA INTERNATIONAL	LT
Epiduo 1 mg/25 mg/g gels	SE/H/0664/001	LT/1/17/4074/003	GALDERMA INTERNATIONAL	LT
Epiduo 1 mg/25 mg/g gels	SE/H/0664/001	LT/1/17/4074/004	GALDERMA INTERNATIONAL	LT
Epiduo 1 mg/25 mg/g gels	SE/H/0664/001	LT/1/17/4074/005	GALDERMA INTERNATIONAL	LT
Epiduo 1 mg/25 mg/g gels	SE/H/0664/001	LT/1/17/4074/006	GALDERMA INTERNATIONAL	LT
Epiduo 1 mg/25 mg/g gels	SE/H/0664/001	LT/1/17/4074/007	GALDERMA INTERNATIONAL	LT
Epiduo 1 mg/25 mg/g gels	SE/H/0664/001	LT/1/17/4074/008	GALDERMA INTERNATIONAL	LT
Epiduo 1 mg/25 mg/g gels	SE/H/0664/001	LT/1/17/4074/009	GALDERMA INTERNATIONAL	LT
Epiduo 1 mg/25 mg/g gels	SE/H/0664/001	LT/1/17/4074/010	GALDERMA INTERNATIONAL	LT
Epiduo 1 mg/25 mg/g geel	SE/H/0664/001	937317	GALDERMA INTERNATIONAL	EE
Epiduo 1 mg/g + 25 mg/g gel	SE/H/0664/001	HR-H-673699134	GALDERMA INTERNATIONAL	HR
Epiduo 1 mg/25 mg / g gel	SE/H/0664/001	9950/2017/01	GALDERMA INTERNATIONAL	RO
Epiduo 1 mg/25 mg / g gel	SE/H/0664/001	9950/2017/02	GALDERMA INTERNATIONAL	RO

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Epiduo 1 mg/25 mg / g gel	SE/H/0664/001	9950/2017/03	GALDERMA INTERNATIONAL	RO
Epiduo 1 mg/25 mg / g gel	SE/H/0664/001	9950/2017/04	GALDERMA INTERNATIONAL	RO
Epiduo 1 mg/25 mg / g gel	SE/H/0664/001	9950/2017/05	GALDERMA INTERNATIONAL	RO
Epiduo 1 mg/25 mg / g gel	SE/H/0664/001	9950/2017/06	GALDERMA INTERNATIONAL	RO
Epiduo 1 mg/25 mg / g gel	SE/H/0664/001	9950/2017/07	GALDERMA INTERNATIONAL	RO
Epiduo 1 mg/25 mg / g gel	SE/H/0664/001	9950/2017/08	GALDERMA INTERNATIONAL	RO
Epiduo 1 mg/25 mg / g gel	SE/H/0664/001	9950/2017/09	GALDERMA INTERNATIONAL	RO
Epiduo 1 mg/25 mg / g gel	SE/H/0664/001	9950/2017/10	GALDERMA INTERNATIONAL	RO
EPIDUO 0,1% I 2,5%, gel	SE/H/0664/001	34009 301 030 9 8	GALDERMA INTERNATIONAL	FR
Epiduo 0.1 %/2.5% gel	SE/H/0664/001	PA0590/030/001	GALDERMA (UK) LIMITED	IE
Epiduo 1 mg/25 mg/g gels	SE/H/0664/001	17-0103	GALDERMA INTERNATIONAL	LV
Epiduo 1 mg/g + 25 mg/g gél	SE/H/0664/001	46/0114/17-S	GALDERMA INTERNATIONAL	SK
Effezel 1 mg/g + 25 mg/g gél	SE/H/0664/001	OGYI-T-23200/01	GALDERMA INTERNATIONAL	HU
Effezel 1 mg/g + 25 mg/g gél	SE/H/0664/001	OGYI-T-23200/02	GALDERMA INTERNATIONAL	HU
Effezel 1 mg/g + 25 mg/g gél	SE/H/0664/001	OGYI-T-23200/04	GALDERMA INTERNATIONAL	HU
Effezel 1 mg/g + 25 mg/g gél	SE/H/0664/001	OGYI-T-23200/06	GALDERMA INTERNATIONAL	HU
Effezel 1 mg/g + 25 mg/g gél	SE/H/0664/001	OGYI-T-23200/08	GALDERMA INTERNATIONAL	HU

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Effezel 1 mg/g + 25 mg/g gél	SE/H/0664/001	OGYI-T-23200/10	GALDERMA INTERNATIONAL	HU
Effezel 1 mg/g + 25 mg/g gél	SE/H/0664/001	OGYI-T-23200/03	GALDERMA INTERNATIONAL	HU
Effezel 1 mg/g + 25 mg/g gél	SE/H/0664/001	OGYI-T-23200/05	GALDERMA INTERNATIONAL	HU
Effezel 1 mg/g + 25 mg/g gél	SE/H/0664/001	OGYI-T-23200/07	GALDERMA INTERNATIONAL	HU
Effezel 1 mg/g + 25 mg/g gél	SE/H/0664/001	OGYI-T-23200/09	GALDERMA INTERNATIONAL	HU
Effezel 1 mg/g + 25 mg/g, gel	SE/H/0664/001	RVG 120233	GALDERMA BENELUX B.V.	NL
Epiduo 0,1%/2,5% γέλη	SE/H/0664/001	022596	GALDERMA HELLAS S.A.	CY
Епидуо 1 mg/ 25 mg/g гел	SE/H/0664/001	20170208 14.06.2017	GALDERMA INTERNATIONAL	BG
Epiduo 0.1% / 2.5% gel	SE/H/0664/001	MA 117/01202	GALDERMA INTERNATIONAL	MT
Epiduo 1 mg/g + 25 mg/g gel	SE/H/0664/001	46/941/16-C	GALDERMA INTERNATIONAL	CZ
Epiduo 0,3% / 2,5% hlaup	SE/H/0664/002	IS/1/16/095/01	GALDERMA NORDIC AB	IS
Epiduo, gel 0,3 %/2,5 %	SE/H/0664/002	56795	GALDERMA NORDIC AB	DK
Epiduo 0,3 % / 2,5 % gel	SE/H/0664/002	15-10930	GALDERMA NORDIC AB	NO
Epiduo 0,3% / 2,5% gel	SE/H/0664/002	53560	GALDERMA NORDIC AB	SE
Epiduo 0,3% / 2,5% geeli	SE/H/0664/002	33715	GALDERMA NORDIC AB	FI
Epiduo 0,3% / 2,5% gel	SE/H/0664/002	33715	GALDERMA NORDIC AB	FI
Epiduo 0.3% / 2.5% gel	SE/H/0664/002	PL 10590/00067	GALDERMA (UK) LIMITED	UK
Epiduo 3 mg/g + 25 mg/g gel	SE/H/0664/002	5694773	LABORATORIOS GALDERMA SA – SUCURSAL EM PORTUGAL	PT
Epiduo 3 mg/g + 25 mg/g gel	SE/H/0664/002	5694815	LABORATORIOS GALDERMA SA – SUCURSAL EM PORTUGAL	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
Epiduo Forte 0,3% / 2,5% gel	SE/H/0664/002	BE503635	GALDERMA BENELUX B.V.	BE
Epiduo Forte 0,3% / 2,5% gel	SE/H/0664/002	BE503635	GALDERMA BENELUX B.V.	BE
Epiduo Forte 0,3 % / 2,5 % Gel	SE/H/0664/002	BE503635	GALDERMA BENELUX B.V.	BE
Epiduo 0,3%/2,5% gel	SE/H/0664/002	038261121	GALDERMA ITALIA S.P.A.	IT
Epiduo Forte 3 mg/g + 25 mg/g gel	SE/H/0664/002	81.359	LABORATORIOS GALDERMA SA	ES
Epiduo Forte, 0,3% + 2,5%, zel	SE/H/0664/002	23639	GALDERMA POLSKA SP. Z O.O.	PL
Epiduo Forte 0,3% / 2,5% gel	SE/H/0664/002	BE503626	GALDERMA BENELUX B.V.	BE
Epiduo Forte 0,3% / 2,5% gel	SE/H/0664/002	BE503626	GALDERMA BENELUX B.V.	BE
Epiduo Forte 0,3 % / 2,5 % Gel	SE/H/0664/002	BE503626	GALDERMA BENELUX B.V.	BE
Epiduo 0,3%/2,5% gel	SE/H/0664/002	038261133	GALDERMA ITALIA S.P.A.	IT
Epiduo 0,3%/2,5% gel	SE/H/0664/002	038261145	GALDERMA ITALIA S.P.A.	IT
Epiduo 0,3%/2,5% gel	SE/H/0664/002	038261158	GALDERMA ITALIA S.P.A.	IT
Epiduo 0,3%/2,5% gel	SE/H/0664/002	038261160	GALDERMA ITALIA S.P.A.	IT
Epiduo 0,3%/2,5% gel	SE/H/0664/002	038261172	GALDERMA ITALIA S.P.A.	IT
Epiduo Forte	SE/H/0664/002	96168.00.00	GALDERMA LABORATORIUM GMBH	DE
EPIDUO 0,3% / 2,5%, gel	SE/H/0664/002	34009 300 811 0 5	GALDERMA INTERNATIONAL	FR
EPIDUO 0,3% / 2,5%, gel	SE/H/0664/002	34009 300 811 1 2	GALDERMA INTERNATIONAL	FR
EPIDUO 0,3% / 2,5%, gel	SE/H/0664/002	34009 300 811 2 9	GALDERMA INTERNATIONAL	FR
EPIDUO 0,3% / 2,5%, gel	SE/H/0664/002	34009 300 811 3 6	GALDERMA INTERNATIONAL	FR
EPIDUO 0,3% / 2,5%, gel	SE/H/0664/002	34009 300 811 5 0	GALDERMA INTERNATIONAL	FR

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EPIDUO 0,3% / 2,5%, gel	SE/H/0664/002	34009 300 811 6 7	GALDERMA INTERNATIONAL	FR
Epiduo Forte (0,3 + 2,5)% γέλη	SE/H/0664/002	50887/02-06-2017	GALDERMA HELLAS S.A.	GR
Epiduo Forte 0,3 % / 2,5 % Gel	SE/H/0664/002	ON PACKAGING LEVEL	GALDERMA BENELUX B.V.	BE
Epiduo Forte 0,3% / 2,5% gel	SE/H/0664/002	ON PACKAGING LEVEL	GALDERMA BENELUX B.V.	BE
Epiduo Forte 0,3% / 2,5% gel	SE/H/0664/002	ON PACKAGING LEVEL	GALDERMA BENELUX B.V.	BE