

Epiduo Gel Prescribing Information (UK & IRE)

Presentation: 0.1% adapalene & 2.5% benzoyl peroxide

Indications: Cutaneous treatment of *acne vulgaris* when comedones, papules and pustules are present in adults, adolescents and children aged 9 Years and over.

Dosage and Administration: A thin film should be applied to the entire acne affected areas once a day in the evening to clean & dry skin. If irritation occurs, apply non-comedogenic moisturisers, use the medication less frequently, suspend use temporarily, or discontinue use altogether. Duration of treatment should be determined on the basis of clinical condition; early signs of improvement usually appear after 1 to 4 weeks. The safety and effectiveness of Epiduo have not been studied in children below 9 years of age.

Contraindications: Hypersensitivity to the active substances or to any of the excipients. If you are pregnant or planning a pregnancy.

Precautions and Warnings: Should not be applied to damaged, broken eczematous or sunburned skin, or come into contact with eyes, mouth, nostrils or mucous membranes (wash immediately with warm water if product enters eyes). Contains propylene glycol (E1520), which may cause skin irritation. Avoid excessive exposure to sunlight or UV light. Avoid contact with any coloured material including hair and dyed fabrics as this may result in bleaching and discolouration.

Pregnancy and Lactation: Epiduo should not be used during pregnancy or in women planning a pregnancy. If the patient becomes pregnant while using Epiduo, treatment should be discontinued. To avoid exposure of an infant to Epiduo, application to the chest should be avoided when breastfeeding.

Interactions: No interaction studies have been conducted with Epiduo. There are no known interactions with other medicinal products which might be used cutaneously and concurrently with Epiduo. However, other retinoids, benzoyl peroxide or drugs with a similar mode of action should not be used concurrently. Caution should be exercised if cosmetics with desquamative, irritant or drying effects are used, as they may produce additive irritant effects with Epiduo. Absorption of adapalene & benzoyl peroxide through human skin is low therefore interaction with systemic medicinal products is unlikely.

Undesirable Effects: Epiduo may cause the following localized adverse reactions: Common ($\geq 1/100$ to $<1/10$): dry skin, irritative contact dermatitis, erythema, skin exfoliation, skin burning sensation and skin irritation. Uncommon ($\geq 1/1000$ to $\leq 1/100$): pruritus and sunburn. Not known: anaphylaxis, allergic contact dermatitis, swelling face, pain of skin, blisters, eyelid oedema, dyspnoea, skin discolouration (hyperpigmentation and hypopigmentation), urticaria, throat tightness and application site burn. Most cases of application site burn were superficial burns but cases with second degree burn or severe burn reactions have been reported. If skin irritation appears after application of Epiduo, the intensity is generally mild or moderate, with local tolerability signs and symptoms (erythema, dryness, scaling, burning and pain of skin (stinging pain)) peaking during the first week and then subsiding spontaneously. Prescribers should consult the summary of product characteristics in relation to other side effects.

Packaging Quantities and Cost: 45g pump UK - £19.53, IE - € 25.53

MA Number: PL 10590/0057(UK), PA 22743/007/001 (IE)

Legal Category: POM

Further Information is Available: Galderma (UK) Limited, Meridien House, 69-71 Clarendon Road, Watford, Herts, WD17 1DS. UK. Tel: +44 (0)1923 208950

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Adverse events should be reported.

For the UK, reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for Yellow Card in the Google Play or Apple App Store.

For Ireland, suspected adverse events can be reported via HPRC Pharmacovigilance, www.hpra.ie;

Adverse events should also be reported to Galderma (UK) Ltd.

E-mail: Medinfo.uk@galderma.com Tel: +44 1 923 208950