

Epiduo 0.3% / 2.5% gel Prescribing Information (UK)

Presentation: 0.3% adapalene & 2.5% benzoyl peroxide

Indications: Cutaneous treatment of *acne vulgaris* when comedones, numerous papules and pustules are present.

Dosage and Administration: A thin layer should be applied to the entire acne affected areas of the face and/or trunk once a day in the evening to clean & dry skin. 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 12 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, sunburnt or eczematous 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. Discontinue in the case of sensitivity reactions. 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. Not recommended for the treatment of severe nodular or deep nodulocystic acne due to risk of insufficient therapeutic response.

Pregnancy and Lactation: Epiduo is contraindicated in pregnancy or women planning a pregnancy. If the patient becomes pregnant while using Epiduo, treatment should be discontinued. A risk to the suckling child cannot be excluded therefore a decision must be made whether to discontinue breast-feeding or to discontinue Epiduo. To avoid exposure of an infant to Epiduo, application to the chest should be avoided when breastfeeding.

Interactions: 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 and benzoyl peroxide through human skin is low, therefore interaction with systemic medicinal products is unlikely.

Undesirable Effects: Epiduo may cause the following localised adverse reactions: Common ($\geq 1/100$ to $<1/10$): Atopic dermatitis, eczema, skin burning sensation, skin irritation, irritative contact dermatitis. Uncommon ($\geq 1/1000$ to $\leq 1/100$): erythema of eyelid, paresthesia, dry skin, rash, pruritus and sunburn. Not known: anaphylactic reaction, skin discolouration, dyspnea, urticaria, allergic contact dermatitis, swelling face, pain of skin, blisters, eyelid oedema, throat tightness and application site burn. If irritation occurs, apply non-comedogenic moisturisers, use the medication less frequently, suspend use temporarily, or discontinue use altogether. Prescribers should consult the summary of product characteristics in relation to other side effects.

Packaging Quantities and Cost: 45g pump UK - £19.53

MA Number: PL 10590/00067

Legal Category: POM

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

Date of Revision: April 2021

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.

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

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