

EPIDUO® GEL

Adapalene / Benzoyl peroxide (0.1%w/w / 2.5%w/w)

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What Epiduo Gel is used for

Epiduo Gel is used for the treatment of acne.

How Epiduo Gel works

Epiduo Gel combines two active substances, which act through different, but complementary, mechanisms of action.

Adapalene:

Adapalene is a chemically stable, naphthoic acid derivative with retinoid-like activity. Biochemical and pharmacological profile studies have demonstrated that adapalene acts in the pathology of Acne vulgaris: it is a potent modulator of cellular differentiation and keratinisation and it has anti-inflammatory properties. Mechanistically, adapalene binds to specific retinoic acid nuclear receptors. Current evidence suggests that topical adapalene normalizes the differentiation of follicular epithelial cells resulting in decreased microcomedone formation. Adapalene inhibits the chemotactic (directional) and chemokinetic (random) responses of human polymorphonuclear leucocytes in in vitro assay models; it also inhibits the metabolism of arachidonic acid to inflammatory mediators. In

vitro studies have shown inhibition of the AP-1 factors and the inhibition of the expression of toll like receptors. This profile suggests that the cell mediated inflammatory component of acne is reduced by adapalene.

Benzoyl peroxide:

Benzoyl peroxide has been shown to have antimicrobial activity; particularly against *P. acnes*, which is abnormally present in the acne-affected pilosebaceous unit. Additionally, benzoyl peroxide has demonstrated exfoliative and keratolytic activities. Benzoyl peroxide is also sebostatic, counteracting the excessive sebum production associated with acne.

Before you use Epiduo Gel

When you must not use it

If you are pregnant or thinking of becoming pregnant. Your doctor can give you more information.

If you are allergic to any of the ingredients in Epiduo Gel. The safety and effectiveness of Epiduo have not been studied in children below 9 years of age.

Pregnancy and lactation

Epiduo is contraindicated in pregnancy, or in women planning a pregnancy. There are no or limited amount of data from the use of adapalene topically in pregnant women. Animal studies by the oral route have shown reproductive toxicity at high systemic exposure. Clinical experience with locally applied adapalene and benzoyl peroxide in pregnancy is limited.

If the product is used during pregnancy, or if the patient becomes pregnant while using this drug, treatment should be discontinued. No study on animal or human milk transfer was conducted after cutaneous application of Epiduo (adapalene / benzoyl peroxide) Gel. Epiduo should be used with caution in breast-feeding women and only on areas away from the

chest.

- Before you start to use it

- Epiduo is for external use only. Epiduo Gel should not be applied to damaged skin, either broken (cuts or abrasions) or eczematous skin.
- Epiduo should not come into contact with the eyes, mouth, nostrils or mucous membranes. If product enters the eye, wash immediately with warm water.
- This product contains propylene glycol (E1520) that may cause skin irritation.
- If a reaction suggesting sensitivity to any component of the formula occurs, the use of Epiduo should be discontinued.
- Excessive exposure to sunlight or UV radiation should be avoided.
- Epiduo should not come into contact with any coloured material including hair and dyed fabrics as this may result in bleaching and discoloration.
- If severe irritation develops, The patient should discontinue use and consult the doctor.

- Taking other medicines

No interaction studies have been conducted with Epiduo.

From previous experience with adapalene and benzoyl peroxide, there are no known interactions with other medicinal products which might be used cutaneously and concurrently with Epiduo.

However, other retinoids or benzoyl peroxide or drugs with a similar mode of action should not be used concurrently.

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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 through human skin is low (see Pharmacokinetic properties), and therefore interaction with systemic medicinal products is unlikely. The percutaneous penetration of benzoyl peroxide in the skin is low and the drug substance is completely metabolised into benzoic acid which is rapidly eliminated.

Therefore, the potential interaction of benzoic acid with systemic medicinal products is unlikely to occur.

How to use Epiduo Gel

- How much to use

Always use Epiduo Gel exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure. A thin film of gel should be applied, with the fingertips, avoiding the eyes and lips.

- When to use it

Epiduo Gel should be applied to the entire acne affected areas once a day in the evening on a clean and dry skin. A thin film of gel should be applied, with the fingertips, avoiding the eyes and lips.

- How long to use it

The duration of treatment should be determined by the Doctor on the basis of the clinical condition. Early signs of clinical improvement usually appear after 1 to 4 weeks of treatment.

- If you forget to use it

Skipping a day of treatment can allow new pimples to begin forming beneath the skin's surface. So, try to make Epiduo Gel part of your regular daily routine. If you miss a day, just start the next day with the same fingertips amount you always use on each of the affected areas of your face and you'll be back on track.

- If you use too much (overdose)

Epiduo is for once-daily cutaneous use only.

In case of accidental ingestion, appropriate symptomatic measures should be taken.

While you are using it

- Things you must do

The skin should be clean and dry before application. You should wash your hands thoroughly after you have used Epiduo Gel.

- Things you must not do

Do not use Epiduo Gel after the expiry date.

- Things to be careful of
Driving and using machines Not relevant.

Side effects

Epiduo may cause the following adverse reactions at the site of application:

- Eyelid oedema
- Throat tightness, shortness of breath
- Dry skin, irritative contact dermatitis, skin irritation, skin burning sensation, erythema, skin exfoliation (scaling)
- Pruritus, sunburn
- Allergic contact dermatitis, swelling face, pain of skin (stinging pain), blisters (vesicles). Application site burn, skin discoloration, hives, serious and severe allergic reaction

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines

(AEFI)]

Storage and Disposal of Epiduo Gel

- Storage

Store below 30°C.

- Disposal

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Product Description

- What it looks like

Gel. A white to very pale yellow opaque gel.

- Ingredients

Active Ingredients

Adapalene 0.1% w/w, benzoyl peroxide 2.5% w/w

Inactive Ingredients

Disodium edetate, docusate sodium, glycerin, poloxamer, propylene glycol (E1520), simulgel 600PHA (copolymer of acrylamide and sodium acryloyldimethyltaurate, isohexadecane, polysorbate 80, sorbitan oleate), purified water.

- MAL number

MAL20102080ARZ

Manufacturer

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Product Registration Holder

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