

Gel 0.1% w/w / 2.5% w/w

Bensolene

(Adapalene + Benzoyl peroxide)

COMPOSITION

Each gram contains:
 Adapalene 0.1% w/w (1mg)
 Benzoyl peroxide 2.5% w/w (25mg)
(Innovator's Specifications)

DESCRIPTION

Bensolene gel contains adapalene 0.1% and benzoyl peroxide 2.5%. Adapalene, a synthetic retinoid, is a naphthoic acid derivative with retinoid-like properties. Benzoyl Peroxide is a highly lipophilic oxidizing agent that localizes in both bacterial and keratinocyte cell membranes.

MECHANISM OF ACTION

Bensolene 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 keratinization 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 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 2. 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.

INDICATIONS

Bensolene gel is indicated for cutaneous treatment of acne vulgaris on the face, chest and back when comedones, papules and pustules are present, and the condition has not responded to first line treatment. It can be used in adults, adolescents and children aged 9 years and over.

DOSEAGE & ADMINISTRATION

Bensolene 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

بیسولین
 (اداپالین + بیٹیزول پراکسائیڈ)
 %۲.۵ / %۰.۱

should be applied, with the fingertips, avoiding the eyes and lips. If irritation occurs, the patient should be directed to apply non-comedogenic moisturizers, to use the medication less frequently (e.g. every other day), to suspend use temporarily, or to discontinue use altogether. 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. The safety and effectiveness of Bensolene have not been studied in children below 9 years of age.

PRECAUTIONS

- Bensolene Gel should not be applied to damaged skin, either broken (cuts or abrasions), eczematous or sunburned.
- Bensolene should not come into contact with the eyes, mouth, nostrils or mucous membranes. If product enters the eye, wash immediately with warm water.
- This medicine contains propylene glycol (E1520), it may cause skin irritation.
- If a reaction suggesting sensitivity to any component of the formula occurs, the use of Bensolene should be discontinued.
- Excessive exposure to sunlight or UV radiation should be avoided.
- Bensolene should not come into contact with any coloured material including hair and dyed fabrics as this may result in bleaching and discoloration.
- Depending upon the severity of local cutaneous adverse reactions, patients should be instructed to use a moisturizer, reduce the frequency of the application of Bensolene, or discontinue use.
- As with other topical retinoids, use of "waxing" as a depilatory method should be avoided on skin treated with Bensolene.
- Avoid concomitant use of other potentially irritating topical products (medicated or abrasive soaps and cleansers, soaps and cosmetics that have strong skin-drying effect and products with high concentrations of alcohol, astringents, spices, or limes).

Paediatric use

The safety and effectiveness of Bensolene have not been studied in children below 12 years of age.

Pregnancy

Bensolene is contraindicated in pregnancy, or in women planning a pregnancy. There are no or limited amount of data from the use of Adapalene typically in pregnant women. If the product is used during pregnancy, or if the patient becomes pregnant while taking this drug, treatment should be discontinued.

Breastfeeding

No study on animal or human milk transfer was conducted after cutaneous application of Bensolene (adapalene / benzoyl peroxide) Gel. No effects on the suckling child are anticipated since the systemic exposure of the breast-feeding woman to Bensolene is negligible. Bensolene can be used during breast-

feeding. To avoid contact exposure of the infant, application of Bensolene to the chest should be avoided when used during breast-feeding.

DRUG INTERACTIONS

No interaction studies have been performed. 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 Bensolene. However, other retinoids or 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 Bensolene. Absorption of Adapalene through human skin is low 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 metabolized into benzoic acid which is rapidly eliminated. Therefore, the potential interaction of benzoic acid with systemic medicinal products is unlikely to occur.

SIDE EFFECTS

If skin irritation appears after application of Bensolene, the intensity is generally mild or moderate, with local tolerability signs and symptoms (erythema, dryness, scaling, burning) and pain of skin (including stinging) peaking during the first two weeks and then subsiding spontaneously. Other side effects may include: Eyelid edema, Anaphylactic reaction, Throat tightness, dyspnea, 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), skin discoloration (hyperpigmentation and hypopigmentation), urticaria, application site burn. Most of the cases of "application site burn" were superficial burns but cases with second degree burn or severe burn reactions have been reported.

CONTRAINDICATIONS

Bensolene gel is contraindicated in following conditions:
 Hypersensitivity to the active substances or to any of the excipients.
 Pregnancy.
 Women planning a pregnancy.

STORAGE & INSTRUCTIONS

Store below 25°C. Protect from heat, sunlight and moisture. Do not freeze or refrigerate. Keep away from the reach of the children. **To be sold on the prescription of a registered medical practitioner only.**

FOR EXTERNAL USE ONLY.

HOW SUPPLIED

15g, 30g tube.

خوراک و طریقہ استعمال:

دن میں ایک دفعہ شام کے وقت متاثرہ حصے پر بیسولین لگائیں یا ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۲۵ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

دھوپ، گرمی، نمی اور نمند ہونے سے بچائیں۔

رنگ بھینچے ہوئے چیزیں نہ رکھیں۔

بچوں کی پہنچ سے دور رکھیں۔

صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔

صرف بیرونی استعمال کے لئے ہے۔

Manufactured by:

PHARMASOL

PRIVATE LIMITED

Plot # 549, Sundar Industrial Estate,
 Lahore, Pakistan.