

# ADAZOYL Gel

# एडाजोयल जेल

## Name and Strength of Active Ingredient (s)

### ADAZOYL:

Hydrous Benzoyl Peroxide BP equivalent to Anhydrous Benzoyl Peroxide

2.5% w/w

Adapalene USP

0.1% w/w

## Product Description

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.

## Pharmacodynamics & Pharmacokinetics

### Pharmacodynamics

#### Adapalene

Adapalene binds to specific retinoic acid nuclear receptors but does not bind to cytosolic receptor protein. Biochemical and pharmacological profile studies have demonstrated that adapalene is a modulator of cellular differentiation, keratinization and inflammatory processes.

#### Benzoyl peroxide

Benzoyl peroxide is an oxidizing agent with bactericidal and keratolytic effects.

### Pharmacokinetic

A pharmacokinetic trial was conducted in 26 adult and adolescent subjects (12 to 33 years of age) with severe acne vulgaris who were treated with once-daily applications during a 4-week period with, on average, 2.3 grams/day (range 1.6 to 3.1 grams/day) of adapalene and benzoyl peroxide topical gel applied as a thin layer to the face, shoulders, upper chest and upper back. After a 4-week treatment, 16 subjects (62%) had quantifiable adapalene plasma concentrations above the limit of quantification of 0.1 ng/mL, with a mean  $C_{max}$  of  $0.16 \pm 0.08$  ng/mL and a mean AUC of  $2.49 \pm 1.21$  ng.h/mL. The most exposed subject had adapalene  $C_{max}$  and AUC of 0.35 ng/mL and 6.41 ng.h/mL, respectively. Excretion of adapalene appears to be primarily by the biliary route. Benzoyl peroxide is absorbed by the skin where it is converted to benzoic acid and eliminated in the urine.

## Indications

- Topical treatment of acne vulgaris in adults and pediatric patients 12 years of age and older.

## Recommended Dose and Administration

- For topical use only. Adapalene and benzoyl peroxide topical gel is not for oral, ophthalmic, or intravaginal use.
- Apply a thin layer of adapalene and benzoyl peroxide topical gel to affected areas of the face and/or trunk once daily after washing.
- Use a pea-sized amount for each area of the face (e.g., forehead, chin, each cheek).
- Wash hands after application as adapalene and benzoyl peroxide topical gel may bleach hair or colored fabrics.
- Avoid in lips and mucous membranes.

## Contraindications

Adapalene and benzoyl peroxide topical gel is contraindicated in patients with a history of hypersensitivity reactions to benzoyl peroxide or any components of the formulation in adapalene and benzoyl peroxide topical gel. Also, it is contraindicated in pregnancy and women planning a pregnancy.

## Warning and Precautions

- Hypersensitivity reactions, including anaphylaxis, angioedema, and urticaria, have been reported with the use of benzoyl peroxide products. If a serious hypersensitivity reaction occurs, discontinue adapalene and benzoyl peroxide topical gel immediately and initiate appropriate therapy.
- Avoid exposure to sunlight, including sunlamps, during the use of adapalene and benzoyl peroxide topical gel. Patients with high levels of sun exposure and those with inherent sensitivity to sun should exercise particular caution. Use of broad spectrum sunscreen products and protective apparel (e.g., hat) are recommended when exposure cannot be avoided. Weather extremes, such as wind or cold, may be irritating to patients under treatment with adapalene and benzoyl peroxide topical gel.
- Erythema, scaling, dryness, and stinging/burning may be experienced with use of adapalene and benzoyl peroxide topical gel. These are

most likely to occur during the first four weeks of treatment, are mostly mild to moderate in intensity, and usually lessen with continued use of the medication.

- Irritant and allergic contact dermatitis may occur. Depending upon the severity of these adverse reactions, patients should be instructed to use a moisturizer, reduce the frequency of the application of adapalene and benzoyl peroxide topical gel, or discontinue use.
- The product should not be applied to cuts, abrasions, eczematous or sun burned skin. As with other retinoids, use of "waxing" as a depilatory method should be avoided on skin treated with adapalene and benzoyl peroxide topical gel.
- 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).

## Drug Interactions

No formal drug-drug interaction studies were conducted with adapalene and benzoyl peroxide gel. Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating, or abrasive agents.

## Special Populations

### Pregnancy Category C

#### Pregnancy, Lactation & Fertility

Orally administered retinoids have been associated with congenital abnormalities. When used in accordance with the prescribing information, topically administered retinoids are generally assumed to result into low systemic exposure due to minimal dermal absorption. However, there could be individual factors (e.g. damaged skin barrier, excessive use) that contribute to an increased systemic exposure.

#### Pregnancy

Adazoyl 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 taking this drug, treatment should be discontinued.

#### Lactation

No study on animal or human milk transfer was conducted after cutaneous application of adapalene & benzoyl peroxide gel. No effects on the suckling child are anticipated since the systemic exposure of the breast-feeding woman to adapalene & benzoyl peroxide gel is negligible. It can be used during breast feeding. To avoid contact exposure of the infant, application of adapalene & benzoyl peroxide gel to the chest should be avoided when used during breast-feeding.

#### Fertility

No human fertility studies were conducted with adapalene and benzoyl peroxide gel. However, no effects of adapalene or benzoyl peroxide on fertility were found in rats in reproductive studies.

#### Pediatric Use

Safety and effectiveness of adapalene and benzoyl peroxide topical gel in pediatric patients under the age of 12 have not been established.

#### Geriatric Use

Clinical studies of adapalene and benzoyl peroxide topical gel did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects.

## Side effects

The most common adverse reactions (incidence  $\geq 1\%$ ) are skin irritation, eczema, atopic dermatitis and skin burning sensation.

## Storage

Protect from direct sunlight and moisture. Store ADAZOYL at less than 25°C. Keep the medication away from children.

## Pack size

15 gm Tube

## Manufactured by:

### Deurali-Janta Pharmaceuticals Pvt. Ltd.



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