Adapalene Gel, 0.3% is a prescription medicine for skin use only (topical) used to treat acne vulgaris in people 12 years of age and older. Acne vulgaris is a condition in which the skin has blackheads, whiteheads and pimples. It is not known if Adapalene Gel, 0.3% is safe and effective in children younger than 12 years of age or in people 65 years of age or older.

**INDICATIONS AND USAGE**

Adapalene Gel, 0.3% is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

**CONTRAINDICATIONS**

Adapalene Gel, 0.3% should not be administered to patients with known hypersensitivity to adapalene or any of the components in the gel vehicle. (3)

**DRUG INTERACTIONS**

Adapalene Gel, 0.3% can be prescribed concomitantly with other topical acne medications or with sulfur, resorcinol, or salicylic acid. (5)

**ADVERSE REACTIONS**

The most frequently reported (≥1%) adverse reactions were: dry skin, skin discomfort, pruritus, desquamation, and sunburn. The following selected adverse reactions occurred in less than 1% of patients:

- Erythema
- Scaling
- Dryness
- Stinging/burning
- Other reactions characterized by symptoms such as pruritus, face edema, eyelid edema, and lip swelling, requiring medical treatment have been reported during postmarketing use of adapalene. A patient should stop using Adapalene Gel, 0.3% and consult a doctor if experiencing allergic or anaphylactoid/anaphylactic reactions.

**HOW TO USE Adapalene Gel, 0.3%**

To report SUSPECTED ADVERSE REACTIONS, contact Valeant Pharmaceuticals at 1-800-874-1000 or www.valeantpharmaceuticals.com.

Adapalene Gel, 0.3% contains adapalene USP, a retinoid, indicated for the topical treatment of acne vulgaris in patients 12 years of age and older. For topical use only. Not for ophthalmic, oral, or inhalation use. (2)

**WARNINGS AND PRECAUTIONS**

Adapalene Gel, 0.3% should not be administrated to children aged 11 years and younger or to pregnant women. (4)

**FULL PRESCRIBING INFORMATION: CONTENTS**

Full prescribing information for Adapalene Gel, 0.3% contains additional important information. (4)

**DOSAGE AND ADMINISTRATION**

Apply a thin layer of Adapalene Gel, 0.3% to affected skin areas, once a day. The majority of cases were mild to moderate in severity, occurred early in treatment and decreased in frequency and severity over the course of the therapy. (10, 11)

**OVERDOSAGE**

Adapalene Gel, 0.3% contains adapalene USP, a retinoid, indicated for the topical treatment of acne vulgaris in patients 12 years of age and older. This product is not a sunscreen. If sun exposure cannot be avoided, weather extremes, such as wind or cold, also may be irritating to patients under treatment with Adapalene Gel, 0.3%.

**PATIENT COUNSELING INFORMATION**

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You should avoid weather extremes such as wind and cold as this may cause irritation to your skin.

No teratogenic effects were seen in rats at oral doses of 0.15 to 5 mg/kg/day adapalene representing up to 6 times the maximum recommended dose (MRHD) of 0.3%.

Adapalene Gel, 0.3% may cause serious side effects including:

Local skin reactions, local skin reactions are most likely to happen during the first 4 weeks of treatment and usually lessen with continued use of Adapalene Gel, 0.3%. Signs and symptoms of local skin reaction include:

- Redness
- Dryness
- Scaling
- Singing or burning

Allergic reactions, Adapalene Gel, 0.3% may cause an allergic reaction that may require medical treatment. Stop using Adapalene Gel, 0.3% and tell your doctor right away if you have any of these symptoms of an allergic reaction:

- hives
- swelling of your face, eyes, lips, tongue or throat
- trouble breathing or chest pain
- skin rash, pruritus, hives, chest pain, edema, and shortness of breath occurs, as these may be signs of allergy or hypersensitivity. Contact the doctor if skin rash, pruritus, hives, chest pain, edema, and shortness of breath occurs, as these may be signs of allergy or hypersensitivity.

Irritation.

During the early weeks of therapy, an apparent exacerbation of acne may occur. This may be due to the action of the medication on previously dormant acne follicles. This should be explained to the patient.

Do not use more than the recommended amount and do not apply more than once daily as this will not produce faster results, but may increase irritation.

The most common side effects of Adapalene Gel, 0.3% are:

- skin pain
- skin peeling
- sunburn

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Adapalene Gel, 0.3%. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Adapalene Gel, 0.3% contains adapalene 0.3% (3 mg/g) in a topical aqueous gel for use in the treatment of acne vulgaris, consisting of carbomer homopolymer type C, edetate disodium, methylparaben, poloxamer 182, propylene glycol, purified water and sodium hydroxide.

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. However, the significance of these findings has not been established in vivo.

Clinical pharmacodynamic studies have not been conducted for Adapalene Gel, 0.3%.

Adapalene is not removed by dialysis and has an apparent volume of distribution of 650 L. The half-life of adapalene following multiple dosing is 3.5 days. The systemic exposure (AUC) of adapalene is dose proportional within the range of 0.15 to 5 mg/kg.

Adapalene is metabolized in the liver via CYP3A4 and CYP2C9. The main metabolites are adapalene acid and 9-oxo-adapalene, which are formed via separate pathways. One of these metabolites is glucuronidated. The metabolic products are eliminated in the urine.

Adapalene Gel, 0.3% is supplied in the following sizes:

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