Adapalene gel
Adaferin®

GEL

For the use ONLY of a Registered Medical Practitioner or a Hospital or a Laboratory.

LEAFLET IS CONTINUALLY BEING UPDATED AND, AS A RESULT SOME INFORMATION MAY NOT BE CURRENT

1. NAME OF THE MEDICINAL PRODUCT

Adapalene 0.1 % Gel
Adaferin®

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Adaferin gel contains respectively 0.1% w/w of adapalene as active ingredient.
Excipients: Gel: methyl parahydroxybenzoate (E218) and propylene glycol. For a full list of excipients, see section 5.1.

3. PHARMACEUTICAL FORM

Gel for cutaneous application

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Adaferin is indicated for the topical treatment of acne vulgaris

4.2 Posology and method of administration

Adaferin should be applied to the acne affected areas once a day at bedtime and after washing.
Ensure that the affected areas are dry before application. A thin film of the product should be applied avoiding the eyes, lips and mucous membranes and the angles of the nose (see 4.4 Special warnings and precautions for use).Clinical improvement is expected to be evident in four to eight weeks of treatment. Further improvement may be assessed after three months of treatment with Adaferin.
Cutaneous safety of Adaferin has been demonstrated over a six- month period. If patients use cosmetics, these should be non-comedogenic and non-astringent.
The safety and effectiveness of Adaferin products have not been studied in children below 12 years of age.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and special precautions for use

If a reaction suggesting sensitivity or severe irritation occurs, use of the medication should be discontinued. If the degree of local irritation warrants, the patient should be directed to use the medication less frequently, to suspend use temporarily until symptoms subside or to discontinue use altogether. Once daily application may be resumed if it is judged that the patient is able to tolerate the treatment.
Adaferin should not come into contact with the eyes, mouth, angles of the nose or mucous membranes. If product enters the eye, wash immediately with warm water. The product should not be applied to either broken (cuts and abrasions), sunburn or eczematous skin, nor should it be used in patients with severe acne involving large areas of the body. Exposure to sunlight and artificial UV irradiation, including sunlamps, should be minimized during use of adapalene. Use of sunscreen products and protective clothing over treated areas is recommended when exposure cannot be avoided.
Adaferin Gel contains :
- methyl parahydroxybenzoate (E218) that can cause allergic reactions (can be arise after the treatment is completed).
- propylene glycol that can be irritating to the skin.

4.5 Interactions with other medicinal products and other forms of interaction

Absorption of adapalene through human skin is low (see 5.2 Pharmacokinetic properties), and therefore interaction with systemic medications is unlikely.
There are no known interactions with other medications which might be used cutaneously and concurrently with Adaferin products. Cutaneous antiacne treatments such as erythromycin (up to 4%) or clindamycin phosphate (1% as the base) solutions or benzoyl peroxide water based gels (up to 10%) may be used in the morning with Adaferin products used at night as there is no mutual degradation or cumulative irritation. However, other retinoids or drugs with a similar mode of action should not be used concurrently with adapalene.
Adaferin Gel has a potential for mild local irritation, and therefore it is possible that concomitant use of peeling agents, abrasive cleansers, strong drying agents, astringents or irritant products (aromatic and alcoholic agents) may produce additive irritant effects.

4.6 Pregnancy and lactation

Pregnancy:
Animal studies by the oral route have shown reproductive toxicity at high systemic exposure. Clinical experience with locally applied adapalene in pregnancy is limited but the few available data do not indicate harmful effects on pregnancy or on the health of the foetus exposed in early pregnancy.
Due to the limited available data and because a very weak cutaneous passage of adapalene is possible, Adaferin should not be used during pregnancy. In case of unexpected pregnancy, treatment should be discontinued.
Lactation:
No study on animal or human milk transfer was conducted after cutaneous application of Adaferin.
No effects on the suckling child are anticipated since the systemic exposure of the breastfeeding woman to Adaferin is negligible. Adaferin can be used during breastfeeding. To avoid contact exposure of the infant, application of Adaferin to the chest should be avoided when used during breast-feeding.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Adverse effects

Adaferin may cause the following adverse drug reactions:

Body System (MeDRA)	Frequency	Adverse Drug Reaction
Skin and subcutaneous tissue disorders	Common (≥1/100 to <1/10)	Dry skin, skin irritation, skin burning sensation, erythema
	Uncommon (≥1/1000 to <1/100)	Dermatitis contact, skin discomfort, sunburn, pruritus, skin exfoliation, acne
	Unknown*	Dermatitis allergic (allergic contact dermatitis), Pain of skin, skin swelling, application site burn**, skin hypopigmentation, skin hyperpigmentation
Eye disorders	Unknown*	eyelid irritation, eyelid erythema, eyelid pruritus, eyelid swelling
Immune system disorders	Unknown*	Anaphylactic reaction, angioedema

*Post marketing surveillance data

** Most of the cases of "application site burn" were superficial burns but cases with second degree burn reactions have been reported

4.9 Overdose

Adaferin is not to be taken orally and are for cutaneous use only. If the medication is applied excessively, no more rapid or better results will be obtained and marked redness, peeling or discomfort may occur.

The acute oral dose of Adaferin products required to produce toxic effects in mice and rats is greater than 10 g/kg. Nevertheless, unless the amount accidentally ingested is small, an appropriate method of gastric emptying should be considered.

5. PHARMACEUTICAL PARTICULARS

5.1 List of excipients

- Propylene glycol ,
- Methyl parahydroxybenzoate,
- Phenoxyethanol
- Carbomer 940(Carbopol 980®)
- Disodium edetate
- Poloxamer 182
- Sodium hydroxide
- Purified water

5.2 Shelf life: 3 years

5.3 Special precautions for storage:

Store at temperature not exceeding 25°C. Do not Freeze. Keep out of reach of children

5.4 Nature and contents of container

White LDPE 15g tube with white PP screw cap.

5.5 Special precautions for disposal and other handling

No special requirements.

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

Manufactured by:

Laboratoires Galderma
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Imported and Marketed by:

Galderma India Private Limited,
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