

PATIENT INFORMATION LEAFLET

Deriva Aqueous Gel (Adapalene Gel 0.1% w/w)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or health care provider or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the leaflet.

In this leaflet:

1. What Adapalene Gel 0.1% is and what it is used for
2. Before you use Adapalene Gel 0.1%
3. How to use Adapalene Gel 0.1%
4. Possible side effects
5. How to store Adapalene Gel 0.1%
6. Further information

1. What Adapalene Gel 0.1% is and what it is used for

The active substance in Adapalene Gel 0.1% is adapalene, which has an anti-inflammatory effect reducing soreness and irritation.

It is used on the face, chest or back for acne, where the skin has lots of blackheads, spots and pimples.

Adapalene Gel 0.1% is only absorbed into the body in very small amounts and has little effect, except on the surface of the skin.

2. Before you use Adapalene Gel 0.1%

Do not use Adapalene Gel 0.1%:

- If you are pregnant
- If you are planning a pregnancy
- If you are allergic to adapalene or any of the other ingredients of this medicine (listed in section 6).

Take special care with Adapalene Gel 0.1%:

- Do not use this medicine on areas where you have cuts or scrapes or if you have a skin condition called eczema.
- Avoid contact with the eyes, mouth or nostrils, and avoid other very sensitive areas of the body. If accidental contact does occur, immediately wash with warm water.
- If you experience sensitivity or irritation when applying this medicine, stop using it and tell your doctor. You may be asked to use the gel less often, or to stop using it until symptoms subside.
- You should avoid exposure to sunlight and artificial UV light whilst using Adapalene Gel 0.1%.

Talk to your doctor or pharmacist if you are not sure.

Using other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Other acne products (containing benzoyl peroxide, erythromycin or clindamycin) may be used with Adapalene Gel 0.1% but they must be applied in the morning and Adapalene Gel 0.1% at night.
- Cosmetics may be used but they must not cause blackheads or dry the skin.

Using with food and drink

No data available.

Pregnancy and breast-feeding

- DO NOT use Adapalene Gel 0.1% if you are pregnant or thinking of becoming pregnant. Your doctor can give you more information.
- If you fall pregnant while using Adapalene Gel 0.1%, the treatment must be discontinued and you should inform your doctor as soon as possible for a further follow-up.
- Adapalene Gel 0.1% can be used during breast-feeding. To avoid contact exposure of the infant, application of Adapalene Gel 0.1% to the chest should be avoided.

Driving and using machines

Adapalene Gel 0.1% has no influence on the ability to drive and use machines.

Important information about some of the ingredients of Adapalene Gel 0.1%

- 40 mg of propylene glycol (E1520) in each gram which is equivalent to 4% w/w, it may cause skin irritation
- methyl parahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed)

3. How to use Adapalene Gel 0.1%

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Adapalene Gel 0.1% is only intended for use in adults and adolescents aged 12 years and over.
- **This medicine is for EXTERNAL USE ONLY.**
- Adapalene Gel 0.1% is applied at night before going to bed, unless your doctor has told you otherwise.
- Thoroughly wash the areas to be treated with water. Make sure the skin is clean and dry before using this medicine.
- Put on a thin film of the gel with your fingertips to the affected areas and rub in gently.
- Don't forget to wash your hands afterwards.
- How long you will have to use this medicine will depend on how quickly your acne improves. After you have used this medicine for three months, it is important that you see your doctor. He or she can then check the improvement of your acne.

If you use more Adapalene Gel 0.1% than you should

If you put too much Adapalene Gel 0.1% on your skin, you will not get rid of your acne any quicker, but your skin may become irritated and red. Some peeling or discomfort could also occur.

In the rare event that you accidentally swallow any of this medicine, seek medical advice.

If you forget to use Adapalene Gel 0.1%

Don't worry if you forget to apply your Adapalene Gel 0.1% at the right time. When you remember, start using this medicine again, in the same way as before.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you stop using Adapalene Gel 0.1%

Do not stop using Adapalene Gel 0.1% without consulting your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Adapalene Gel 0.1% may cause the following side effects at the site of application.

Contact a doctor right away if you notice any of the following symptoms-you may need urgent medical treatment: Swelling of the face, lips or throat which makes it difficult to swallow or breathe, rash, itching, hives and dizziness. This could be a sign of angioedema or a severe allergic reaction (frequency not known, cannot be estimated from the available data).

Common: may affect up to 1 in 10 people

- dry skin
- irritation of the skin
- burning sensation of the skin
- redness of the skin (erythema)

Uncommon: may affect up to 1 in 100 people

- local skin reaction (contact dermatitis)
- skin discomfort
- sunburn
- itching of the skin (pruritus)
- peeling skin (exfoliation)
- acne

Not known: frequency cannot be estimated from the available data

- allergic contact reaction
- pain or swelling of the skin
- irritation, redness, itching or swelling of the eyelids
- darkening of fair skin
- lightening of darker skin
- application site burn

Application site burns (mostly superficial burns but also second degree or severe burn) have been reported.

Reporting of side effects

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

5. How to store Adapalene Gel 0.1%

Store below 30°C. Protect from freezing and light.

6. Further information

Adapalene Gel 0.1% Contains:

The active substance is Adapalene

The other ingredients are Di-Sodium Edetate, Carbomer 940 (Carbopol 940), Propylene Glycol Methyl Hydroxybenzoate, Phenoxyethanol, Poloxamer 407, Sodium Hydroxide, Purified Water

Name and full physical address of Marketing Authorization Holder and Manufacturing site:

Glenmark Pharmaceuticals Limited B/2
Mahalaxmi Chambers,
22, Bhulabhai Desai Road, Mumbai-400026, (India).
At: Plot no. E-37, 39, D-Road, MIDC, Satpur, Nashik
422007, Maharashtra State, India.

This leaflet was last approved in (MM/YYYY)

10.12.2023