

Differin 0.1% w/w Gel

a d a p a l e n e

G E L



PACKAGE LEAFLET: INFORMATION FOR THE USER

Differin 0.1% w/w Gel

Adapalene

Read all of this leaflet carefully before you start using this medicine.

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

In this leaflet:

1. What Differin is and what it is used for
2. Before you use Differin
3. How to use Differin
4. Possible side effects
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1. What Differin is and what it is used for

- The active substance in Differin 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.
- Differin 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 Differin

Do not use Differin if you are:

- Allergic (hypersensitive) to adapalene or any of the other ingredients of Differin (see section 6 for other ingredients).

Take special care with Differin

- Do not use Differin 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.
- Avoid exposure to strong sunlight and artificial UV light.
- If you experience sensitivity or irritation when applying Differin, stop using it and tell your doctor. You may be asked to use the gel less often, or to stop using it for a short time.

Using other medicines

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

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

- Differin should not be used during pregnancy. If you fall pregnant while taking Differin, the treatment must be discontinued and you should inform your doctor as soon as possible for a further follow-up.
- Differin can be used during breast-feeding. To avoid contact exposure of the infant, application of Differin to the chest should be avoided.

Ask your doctor or pharmacist for advice before taking any medicine.

Important information about some of the ingredients of Differin

The ingredient propylene glycol (E1520) may cause skin irritation and methyl parahydroxybenzoate (E218) may cause allergic reactions (possibly delayed).

3. How to use Differin

Always use Differin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Differin is only intended for use in adults and adolescents aged 12 years and over.
- **Differin is for EXTERNAL USE ONLY.**
- Differin 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 Differin.
- 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 Differin will depend on how quickly your acne improves. After you have used Differin 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 Differin than you should or accidentally swallow the gel

- If you put too much Differin 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 product, seek medical advice.

If you forget to use Differin

Don't worry if you forget to apply your Differin at the right time. When you remember, start using the product again, in the same way as before.

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

4. Possible side effects

Like all medicines, Differin can cause side effects, although not everybody gets them.

Differin Gel may cause the following side effects at the site of application.

Common side effects (occur in less than 1 in 10 patients)

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

Uncommon side effects (occur in less than 1 in 100 patients)

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

Other effects include pain or swelling of the skin and irritation, redness, itching or swelling of the eyelids.

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

5. How to store Differin

- Keep out of the reach and sight of children.
- Do not use Differin after the expiry date which is stated on the tube and carton. The expiry date refers to the last day of that month.
- Keep the medicine in its original container. Do not store above 25°C. Do not freeze.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Differin contains

The active substance is adapalene. Differin contains 0.1% w/w of adapalene and the other ingredients are carbomer 940, propylene glycol (E1520), poloxamer 182, disodium edetate, methylparahydroxybenzoate (E218), phenoxyethanol, sodium hydroxide and purified water.

What Differin looks like and contents of the pack

Differin is a white gel. It is available in tubes of 30 g, 45 g or 50 g on prescription from your doctor.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Galderma (UK) Limited, Meridien House, 69-71 Clarendon Road, Watford, Herts., WD17 1DS UK. (PL 10590/0015)

Manufacturer: Laboratoires Galderma, ZI-Montdésir, 74540 Alby-sur-Chéran, France.

Differin is a Prescription Only Medicine.

This leaflet was last approved in 10/2008.

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