PACKAGE LEAFLET: INFORMATION FOR THE USER
Differin 0.1% w/w Cream
Adapalene

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, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness 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 this leaflet. See section 4.
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What is in this leaflet:

1. What Differin is and what it is used for
2. What you need to know before you use Differin
3. How to use Differin
4. Possible side effects
5. How to store Differin
6. Contents of the pack and other information

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 may have 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. What you need to know before you use Differin

Do not use Differin:

- 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).

Warnings and precautions

- Do not use this medicine on areas where you have cuts or scrapes or on sunburnt skin or if you have a skin condition called eczema.
- Avoid contact with the eyes, mouth or angles of the nose, and avoid other very sensitive areas of your body. If accidental contact does occur, immediately wash with warm water.
- Avoid exposure to strong sunlight and artificial UV light. Use of sunscreen products and protective clothing over the treated area is recommended.
- If you experience sensitivity or irritation when applying this medicine, stop using it and tell your doctor. You may be asked to use the cream less often, or to stop using it until symptoms subside.

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

Other medicines and Differin
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 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.

Pregnancy, breast-feeding and fertility

- DO NOT use Differin if you are pregnant or thinking of becoming pregnant. Your doctor can give you more information.
- If you fall pregnant while using 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.

Differin contains:
Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

3. How to use Differin

Always use this medicine exactly as your doctor has told you. 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.
- **This medicine 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 this medicine.
- Put a thin film of the cream with your fingertips on to the affected areas and rub in gently.
- Do not 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 3 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 any of the cream

- 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 medicine, 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 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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Differin Cream 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 may make 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)
- flare up of 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.medicinesauthority.gov.mt/adrportal By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Differin

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine 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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Differin contains
The active substance is adapalene. Differin contains 0.1% w/w of adapalene and the other ingredients are carbomer 934P, macrogol-20 methyl glucose sesquistearate, glycerol (E422), natural squalane, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), disodium edetate, methyl glucose sesquistearate, phenoxyethanol, cyclomethicone, sodium hydroxide and purified water.

What Differin looks like and contents of the pack
Differin is a white cream. It is available in tubes of 5 g, 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 International, Tour Europlaza La Defense 4, 20 Avenue Andre Prothin 92927 La Defense Cedex France
Manufacturer: Laboratoires Galderma, ZI-Montdésir, 74540 Alby-sur-Chéran, France.

Differin is a Prescription Only Medicine.

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