

APPROVED PATIENT INFORMATION LEAFLET**PATIENT INFORMATION LEAFLET DIFFERIN GEL**

Read all of this leaflet carefully before you start using DIFFERIN GEL.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- DIFFERIN GEL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS:

Schedule 3

PROPRIETARY NAME AND DOSAGE FORM:**DIFFERIN GEL**

Adapalene

1. WHAT DIFFERIN GEL CONTAINS

DIFFERIN GEL contains the active ingredient adapalene 0,1 % w/w and the other ingredients are carbomer 940, propylene glycol, poloxamer 182, disodium edetate, sodium hydroxide and purified water. Preservatives: 0,1 % (m/m) methyl paraben and 0,25 % (m/m) phenoxyethanol.

2. WHAT DIFFERIN GEL IS USED FOR

- The active ingredient in DIFFERIN GEL is adapalene. DIFFERIN GEL is used for the treatment of acne where blackheads and whiteheads, spots and pimples appear.

3. BEFORE YOU USE DIFFERIN GEL***Do not use DIFFERIN GEL:***

- If you have a reaction to any of its ingredients.

Take special care with DIFFERIN GEL:

- If you are a woman capable of having children i.e. you have not gone through the menopause, then you must use effective contraception whilst using DIFFERIN GEL.
- When using DIFFERIN GEL on the face, don't get it into your eyes, mouth or angles of the nose, and avoid other very sensitive areas of your body.
- Avoid exposure to strong sunlight and artificial UV light. Use of sunscreen products and protective clothing over the treated area is recommended.
- Other acne products (containing benzoyl peroxide, erythromycin or clindamycin) may be used with DIFFERIN GEL, but they must be applied in the morning and DIFFERIN GEL at night.
- Cosmetics may be used but they must be non-comedogenic and non-astringent, i.e. they should not cause blackheads or dry the skin.
- Using more than the recommended amount of DIFFERIN GEL may result in very red and sore skin.
- DIFFERIN GEL is best applied to your skin after washing and drying.
- Do not use DIFFERIN GEL in children under the age of 12 years.
- Do not use DIFFERIN GEL on areas where you have cuts or scrapes or on sunburnt skin.
- If you experience sensitivity or irritation when applying DIFFERIN GEL, stop using it and tell your doctor. You may be asked to use the cream less often, or to stop using it for a short time.
- The ingredients: methylparaben (E218) and propylparaben (E216) may cause allergic reactions which can possibly be delayed.

If you are using other medicines make sure you tell your doctor.

Pregnancy and breastfeeding

Pregnancy

DIFFERIN GEL should not be used during pregnancy.

If you fall pregnant while using DIFFERIN GEL, the treatment must be stopped immediately and you should inform your doctor as soon as possible for a further follow-up.

Breastfeeding

It is not known whether adapalene is secreted in animal or human milk.

DIFFERIN GEL should not be used during breastfeeding.

If you are breastfeeding while using DIFFERIN GEL, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery

DIFFERIN GEL should not have any influence on the ability to drive and use machines.

Using other medicines with DIFFERIN GEL

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

4. HOW TO USE DIFFERIN GEL

Always use DIFFERIN GEL as your doctor has instructed you. You check with your doctor or pharmacist if you are unsure.

- DIFFERIN GEL 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 GEL.
- Put a thin film of the gel 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 DIFFERIN GEL will depend on how quickly your acne improves. After you have used DIFFERIN GEL for 3 months, it is important that you see your doctor. He or she can then check the improvement of your acne.
- Don't worry if you forget to apply your DIFFERIN GEL at night time. When you remember, start using DIFFERIN GEL again, in the same way as before.
- **Do not share DIFFERIN GEL prescribed for you with others.**

If you use more DIFFERIN GEL than you should:

- If you follow the instructions for use it should not be possible to use too much or overdose.
- **DIFFERIN GEL is not to be taken by mouth and is for use on the skin only. If, in the rare event that DIFFERIN GEL is accidentally swallowed, consult your doctor or pharmacist. If neither is available, rush to the nearest hospital or poison control centre.**

- If you put too much DIFFERIN GEL 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.

5. POSSIBLE SIDE-EFFECTS

Not all side-effects reported for DIFFERIN GEL are included in this leaflet. Should your general health worsen while taking, DIFFERIN GEL please consult your doctor, pharmacist or other healthcare professional for advice.

DIFFERIN GEL may cause the following side-effects at the site of application.

Frequent side-effects:

- Dry skin
- Irritation of the skin
- Burning sensation of the skin
- Redness of the skin (erythema)

Less frequent side-effects:

- Local skin reaction (contact dermatitis)
- Skin discomfort
- Sunburn
- Itching of the skin (pruritus)
- Peeling skin (exfoliation)
- Flare-up of acne

Other effects include allergic local skin reaction (allergic contact dermatitis), pain or swelling of the skin and irritation, redness, itching or swelling of the eyelids.

- If you have any of these or any other unusual effects, and they are bad enough to trouble you, consult your doctor.

6. STORING AND DISPOSING OF DIFFERIN GEL

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Keep the medicine in its original container. Do not store above 25 °C. Do not freeze. Keep tube well closed.

Always check the expiry date which is shown on the tube and carton at the time of receipt. Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF DIFFERIN GEL

DIFFERIN GEL is available in plastic tubes of 30 g on prescription from your doctor.

8. IDENTIFICATION OF DIFFERIN GEL

DIFFERIN GEL: A smooth, white gel.

9. REGISTRATION NUMBER / REFERENCE NUMBER

DIFFERIN GEL: 29/13.12/0606

10. NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER

Galderma Laboratories South Africa (Pty) Ltd

17 Muswell Road South

Bryanston

2021

11. DATE OF PUBLICATION

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