

APPROVED PATIENT INFORMATION LEAFLET**PATIENT INFORMATION LEAFLET DIFFERIN CREAM**

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- DIFFERIN CREAM 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 CREAM**

Adapalene

1. WHAT DIFFERIN CREAM CONTAINS

DIFFERIN CREAM contains the active ingredient adapalene 0,1 % w/w and the other ingredients are carbomer 934P, cyclomethicone, disodium edetate, glycerol (E422), macrogol-20 methyl glucose sesquistearate, methyl glucose sesquistearate, natural squalane, purified water and sodium hydroxide.

Preservatives: 0,2 % (m/m) methyl parahydroxybenzoate (E218), 0,1 % (m/m) propyl parahydroxybenzoate (E216) and 0,5 % (m/m) phenoxyethanol.

2. WHAT DIFFERIN CREAM IS USED FOR

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

3. BEFORE YOU USE DIFFERIN CREAM

Do not use DIFFERIN CREAM:

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

Take special care with DIFFERIN CREAM:

- 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 CREAM.
- When using DIFFERIN CREAM 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 CREAM, but they must be applied in the morning and DIFFERIN CREAM 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 CREAM may result in very red and sore skin.
- DIFFERIN CREAM is best applied to your skin after washing and drying.
- Do not use DIFFERIN CREAM in children under the age of 12 years.
- Do not use DIFFERIN CREAM on areas where you have cuts or scrapes or on sunburnt skin.
- If you experience sensitivity or irritation when applying DIFFERIN CREAM, 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 CREAM should not be used during pregnancy.

If you fall pregnant while using DIFFERIN CREAM, 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 CREAM should not be used during breastfeeding.

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

Driving and using machinery

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

Using other medicines with DIFFERIN CREAM

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

4. HOW TO USE DIFFERIN CREAM

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

- DIFFERIN CREAM 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 CREAM.
- 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 DIFFERIN CREAM will depend on how quickly your acne improves. After you have used DIFFERIN CREAM 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 CREAM at night time. When you remember, start using DIFFERIN CREAM again, in the same way as before.
- **Do not share DIFFERIN CREAM prescribed for you with others.**

If you use more DIFFERIN CREAM than you should:

- If you follow the instructions for use it should not be possible to use too much or overdose.
- **DIFFERIN CREAM is not to be taken by mouth and is for use on the skin only. If, in the rare event that DIFFERIN CREAM 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 CREAM 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 CREAM are included in this leaflet.

Should your general health worsen while taking, DIFFERIN CREAM please consult your doctor, pharmacist or other healthcare professional for advice.

DIFFERIN CREAM 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 CREAM

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 CREAM

DIFFERIN CREAM is available in aluminium tubes of 30 g or 60 g on prescription from your doctor.

8. IDENTIFICATION OF DIFFERIN CREAM

DIFFERIN CREAM: A smooth, white, shiny cream.

9. REGISTRATION NUMBER / REFERENCE NUMBER

DIFFERIN CREAM: 32/13.12/0476

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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