

Applicant:	GALDERMA LABORATORIES SOUTH AFRICA (PTY) LTD.
Proprietary name:	DIFFERIN GEL
Dosage form and strength:	1 mg adapalene per gram gel
Registration Number	29/13.12/0606

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

DIFFERIN GEL

Adapalene

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, pharmacist, nurse or other health care provider
- 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.

What is in this leaflet

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

1. What DIFFERIN GEL is and what it is used for

DIFFERIN GEL is an acne preparation.

DIFFERIN GEL is used for the treatment of acne where blackheads and whiteheads, spots and pimples appear.

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2. What you need to know before you use DIFFERIN GEL

Always tell your health care provider if you are taking any other medicine. If you are pregnant or breast feeding your baby please consult your health care provider for advice before using this medicine.

Do not use DIFFERIN GEL

- Hypersensitivity to the active or any of the excipients listed in section 6.
- Pregnancy (see section 4.6)
- Women planning a pregnancy

Warnings and precautions

Take special care with DIFFERIN GEL:

Tell your doctor or health care provider before using 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 on areas where you have cuts or scrapes or on sunburnt skin.

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- 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]~~ gel 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.

Children

Do not use DIFFERIN GEL in children under the age of 12 years.

Other medicines and DIFFERIN GEL

Always tell your health care provider if you are taking or using any other medicine. (This includes all complementary or traditional medicines.)

- There are no known interactions with other medications which might be used cutaneously and concurrently with Differin Cream and Differin Gel, however, other retinoids or medicines with a similar mode of action should not be used concurrently.
- Safety of use during repeated exposure to sunlight or UV irradiation has not been established. Exposure to excessive sunlight or UV irradiation should therefore be avoided.
- Absorption of adapalene through human skin is low, and therefore interaction with systemic medication is unlikely
- DIFFERIN GEL has a potential for local irritation and therefore it is possible that concomitant use of peeling agents, astringents or irritant products may produce additive irritant effects.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding, think that you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before you use this medicine.

Orally administered retinoids have been associated with congenital abnormalities. When used in accordance with the prescribing information, topically administered retinoids are generally assumed to result in low systemic exposure due to minimal dermal absorption. However, there could be

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individual factors (e.g. damaged skin barrier, excessive use) that contribute to an increased systemic exposure.

Pregnancy

Differin Gel is contraindicated (see section 4.3) in pregnancy, or in women planning a pregnancy. DIFFERIN GEL should therefore 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 machines:

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

DIFFERIN GEL contains preservatives and propylene glycol

- Preservatives: Methylparaben 0,1 % (m/m) and phenoxyethanol 0,25 %.(m/m)
- Methyl parahydroxybenzoate (E218) can cause allergic reactions (can arise after the treatment is completed)
- Propylene glycol can be irritating to the skin.

3. How DIFFERIN GEL is used

Do not share medicines prescribed for you with any other person.

Always use DIFFERIN GEL exactly as your doctor has-told you.

Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with DIFFERIN GEL will last.

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If you have the impression that DIFFERIN GEL is too strong or too weak, tell your doctor or pharmacist.

- 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.

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, contact the nearest hospital or poison 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.

If you forgot to use DIFFERIN GEL

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.

If you stop using DIFFERIN GEL

Your doctor will tell you how long your treatment with DIFFERIN GEL will last

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4. Possible side effects

DIFFERIN GEL can have side effects.

Not all side-effects reported for DIFFERIN GEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using, DIFFERIN GEL, please consult your health care provider for advice.

DIFFERIN GEL contains contains methyl parahydroxybenzoate (E218) which can cause allergic reactions (can arise after the treatment is completed)

DIFFERIN GEL contains propylene glycol which can be irritating to the skin.

If any of the following happens, stop using DIFFERIN GEL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Fainting
- Rash or itching

These are all very serious side effects.

If you have them, you may have had a serious allergic reaction to DIFFERIN GEL.

You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

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:

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

Frequency unknown side-effects:

- Anaphylactic reaction, with symptoms such as swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Angioedema with symptoms such as fainting, itching
- Allergic contact dermatitis
- Skin pain
- Skin swelling
- Application site burn
- Skin hypopigmentation
- Skin hyperpigmentation
- Eyelid irritation
- Eyelid redness (erythema)
- Eyelid itching (pruritus)
- Eyelid swelling

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store DIFFERIN GEL

Keep the medicine in its original container.

Store at or below 25 °C. Do not refrigerate.

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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).

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

6. Contents of the pack and other information

What DIFFERIN GEL contains:

DIFFERIN GEL is a gel to apply to your skin.

The active substance is:

Adapalene 1 mg/g [0,1 % (m/m)]

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.

What DIFFERIN GEL looks like and contents of the pack

DIFFERIN GEL: A smooth, white gel.

Pack contains:

DIFFERIN GEL is available in plastic tubes of 30 g fitted with a white polypropylene cap on prescription from your doctor.

Single tubes are packed in folded carton boxes.

Holder of Certificate of registration:

Galderma Laboratories South Africa (Pty) Ltd

Nicol Main Office Park,

Block C, First Floor,

FutureSpace,

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2 Bruton Road,

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