

DIFFERIN[®] GEL

Adapalene (0.1% w/w)

What is in this leaflet:

1. What Differin Gel is used for
2. How Differin Gel works
3. Before you use Differin Gel
4. How to use Differin Gel
5. While you are using Differin Gel
6. Side effects
7. Storage and Disposal of Differin Gel
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Differin Gel is used for

Differin Gel is a prescription medicine for skin use only (topical) used to treat acne vulgaris in people 12 years of age and older.

Acne vulgaris is a condition in which the skin has blackheads, whiteheads and pimples.

It is not known if Differin Gel is safe and effective in children younger than 12 years of age.

How Differin Gel works

The active substance in Differin Gel is adapalene which has an anti-inflammatory effect reducing soreness and irritation.

Before you use Differin Gel**- When you must not use it**

Do not use Differin Gel if you are allergic to adapalene or any of the ingredients in Differin Gel. See the end of this Consumer Information Leaflet for a complete list of ingredients in Differin Gel.

- Before you start to use it

Before you use Differin Gel, tell your doctor if you:

- have other skin problems, including eczema, seborrhoeic skin inflammation
- have any other medical conditions
- have severe forms of acne

Pregnancy and breastfeeding

It is not known if Differin Gel can harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.

It is not known if Differin Gel passes into your breast milk and if it can harm your baby. Talk to your doctor about the best way to feed your baby if you use Differin Gel.

To avoid contact exposure of the infant, application of Differin Gel to the chest should be avoided.

- Taking other medicines

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

Especially tell your doctor if you use any other medicine for acne.

However, topical anti-acne treatments, e.g. erythromycin or clindamycin phosphate solutions or benzoyl peroxide water based gels, may be used in the morning when Differin Gel is used at night.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How to use Differin Gel

- Wash the area where Differin Gel will be applied and pat dry.
- Tube: Squeeze a small amount onto your fingertips and spread a thin layer over the entire face and any other affected areas.

- How much to use

Use Differin Gel exactly as your doctor tells you to use it. Differin Gel is for skin use only. Do not use Differin Gel in or on your mouth, eyes, or vagina.

Apply Differin Gel 1 time a day.

- When to use it

Differin Gel should be applied to the acne affected area once a day before retiring and after washing, unless your doctor has instructed otherwise.

- How long to use it

How long you will have to use Differin Gel will depend on how quickly your acne improves. After you have used Differin Gel, it is important that you see your doctor. He or she can then check the improvement of your acne.

- If you forget to use it

Don't worry if you forget to apply your Differin Gel 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.

- If you use too much (overdose)

Do not use more Differin Gel than you need to cover the treatment area. Using too much Differin Gel or using it more than 1 time a day may increase your chance of skin irritation such as marked redness, peeling or discomfort.

While you are using Differin Gel**- Things you must do**

- You should avoid spending time in sunlight or artificial sunlight, such as tanning beds or sunlamps. Differin Gel may enhance the development of skin cancers caused by ultraviolet light.
- You should wear sunscreen and wear a hat and clothes that cover the areas treated with Differin Gel if you have to be in sunlight.
- You should avoid skin products that may dry or irritate your skin such as harsh soaps, astringents, cosmetics that have strong skin drying effects and products containing high levels of alcohol. Cosmetics may be used but they must not cause blackheads or dry the skin.

DIFFERIN[®] GEL

Adapalene (0.1% w/w)

- Things you must not do

Do not use Differin Gel after the expiry date.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machine. If the gel makes you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side Effects

Differin Gel may cause serious side effects including:

- Local skin reactions. Local skin reactions are most likely to happen during the first 4 weeks of treatment and usually lessen with continued use of Differin Gel. Signs and symptoms of local skin reaction include:
- Redness
- Dryness
- Scaling
- Stinging or burning
- Allergic reactions.

Differin Gel may cause an allergic reaction that may require medical treatment. Stop using Differin Gel and tell your doctor right away if you have any of these symptoms of an allergic reaction:

- Skin rash, itching or hives
- Trouble breathing or chest pain
- Swelling of your face, eyes, lips, tongue or throat

You may use a moisturizer for relief of dry skin or irritation, however you should avoid products that contain oil.

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Differin Gel. For more information, ask your doctor or pharmacist.

You may report any side effect or adverse drug reaction directly to the National Centre for Adverse Drug

Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Differin Gel

- Storage

Store at room temperature not exceeding 25°C.

Do not freeze Differin Gel.

Keep out of the reach and sight of children.

- Disposal

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

Product Description

- What it looks like

Differin Gel is a white gel. It is available in tubes of 15, 30 and 60g laminate tube.

Not all pack sizes may be marketed.

- Ingredients

- Active ingredient: Adapalene
- Inactive ingredients: carbomer, edetate disodium, methylparaben, poloxamer 182, propylene glycol, phenoxyethanol, purified water and sodium hydroxide.

- MAL Number

MAL20001212AZ

Manufacturer

Labs Galderma
Z.A. De Montd'e Sir,
74540 Alby-Sur-Cheran,
France

Product Registration Holder

Zuellig Pharma Sdn. Bhd.
No 15, Persiaran Pasak Bumi,
Seksyen U8, Perindustrian Bukit
Jelutong, 40150 Shah Alam,
Selangor Darul Ehsan, Malaysia

Date of Revision

11/5/2016

Serial Number

BPFK(R4/1)180416/00112