

Package leaflet: Information for the user

Adapalene/ Benzoyl Peroxide 0.1 % + 2.5 % gel

adapalene/ benzoyl peroxide

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 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.

What is in this leaflet:

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

1. What Adapalene / Benzoyl Peroxide is and what it is used for

This medicine is used for the treatment of acne.

This gel combines two active ingredients, adapalene and benzoyl peroxide, which work together but in different ways:

Adapalene belongs to a group of products known as retinoids and acts specifically on the skin processes that cause acne. The other active ingredient, benzoyl peroxide, works as an antimicrobial agent and by softening and peeling the outer layer of the skin.

2. What you need to know before you use Adapalene / Benzoyl Peroxide

Do not use this medicine:

- if you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6.)
- if you are pregnant
- if you are planning a pregnancy.

Warnings and precautions

You should not use this medicine on areas where you have cuts, scrapes, sunburn or eczema.

Make sure this medicine does not get into your eyes, mouth or nostrils, and other very sensitive areas of the body. Should this occur wash these areas immediately with plenty of warm water.

Avoid excessive exposure to sunlight and UV lamps.

Avoid getting this medicine on your hair or coloured fabrics as it may bleach them and wash your hands thoroughly after you have used the medicine.

This medicine contains 40mg propylene glycol in 1g of gel.

Talk to your doctor or pharmacist before using this medicine.

Other medicines and Adapalene / Benzoyl Peroxide

Do not use other acne products (containing benzoyl peroxide and/or retinoids) at the same time as this medicine.

Avoid using this medicine at the same time as cosmetics that are irritant, drying or exfoliate the skin.

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility

DO NOT use this medicine if you are pregnant or thinking of becoming pregnant. Your doctor can give you more information.

If you fall pregnant while taking this medicine, the treatment must be discontinued and you should inform your doctor as soon as possible for a further follow-up.

This medicine can be used during breast-feeding. To avoid contact exposure of the infant, application of This medicine to the chest should be avoided.

Driving and using machines

Not relevant

This medicine contains propylene glycol

This medicine contains 40mg propylene glycol (E1520) in each gram which is equivalent to 4 % w/w.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

3. How to use Adapalene / Benzoyl Peroxide

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

This medicine is only intended for use in adults, adolescents and children aged 9 years and over. This medicine is for external use only.

Apply a thin film of gel evenly over acne affected areas once a day at bedtime, avoiding the eyes, lips and nostrils. The skin should be clean and dry before application. You should wash your hands thoroughly after you have used this medicine.

Tube: One fingertip provides approximately 2.5cm of gel corresponding to an average gel weight around 0.5g.

Bottle: One pump provides an average gel weight around 0.5 g.

Your doctor will tell you how long you will need to use this medicine.

If you feel that the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist.

If you experience persistent irritation when applying this medicine, contact your doctor.

You may be asked to apply a moisturizer, to use the gel less often or to stop for a short time, or to stop using the gel altogether.

If you use more Adapalene / Benzoyl Peroxide than you should

If you use more of this medicine than you should on your skin, you will not get rid of your acne quicker, but your skin may become irritated and red.

Please contact your doctor or the hospital:

- if you have used more of this medicine than you should

- if a child has accidentally taken this medicine
- if you accidentally swallow this medicine.

Your doctor will advise you on action to be taken.

If you forget to use Adapalene / Benzoyl Peroxide

Do not apply a double dose to make up for forgotten individual doses.

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.

Stop using the product and seek immediate medical attention if you develop throat tightness or swelling of the eyes, face, lips or tongue, feel faint, or have difficulty breathing. Stop using this medicine if you develop hives or itching of the face or body. The frequency with which these side effects occur is not known.

Common side effects (may affect up to 1 in 10 people):

Dry skin, local skin rash (irritative contact dermatitis), burning sensation, irritation of the skin, redness, scaling.

Uncommon side effects (may affect up to 1 in 100 people):

Itching of the skin (pruritus), sunburn.

Not known (frequency cannot be estimated from the available data):

Swelling of the face, allergic contact reactions, swelling of the eyelid, tightness in the throat, pain on the skin (stinging pain), blisters (vesicles), difficulty in breathing, skin discolouration (change in skin colour), application site burn.

If skin irritation appears after application of this medicine, it is generally mild to moderate, with local signs such as redness, dryness, scaling, burning and pain on the skin (stinging pain), which peak during the first week and resolve without additional treatment.

Application site burns, mostly superficial but more severe cases involving blistering, have been reported.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Adapalene / Benzoyl Peroxide

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 carton after "EXP". The expiry date refers to the last day of that month.

Store below 30 °C.

After first opening this medicine can be used for 6 months, if stored below 25 °C.

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 this medicine contains

The active substances are adapalene and benzoyl peroxide.

One gram of gel contains 1mg of adapalene and 25mg of anhydrous benzoyl peroxide (as benzoyl peroxide, hydrous).

The other ingredients are disodium edetate, docusate sodium, poloxamer 124, glycerol, propylene glycol (E1520), sorbitan oleate, sepineo P 600 (acrylamide/sodium acryloyldimethyl taurate copolymer in isohexadecane with polysorbate 80), purified water.

What this medicine looks like and contents of the pack

Adapalene / Benzoyl Peroxide 0.1% + 2.5 % gel is a white to very pale yellow opaque gel.

Adapalene / Benzoyl Peroxide 0.1% + 2.5% gel can be packed as:

15g or 30g of gel in a laminated tube with aluminium barrier with protective membrane and a plastic polypropylene closure, in a carton.

30 g, 45g or 60g of gel in an airless, white, polypropylene bottle with airless plastic snap-on pump equipped with actuator and plastic cap, in a carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Penlan Pharmaceuticals Ltd, 5 The Heights, Weybridge, KT13 0NY, UK

Manufacturer

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