

Consumer Medicine Information

BENZAC AC[®]

Benzoyl peroxide

What is in this leaflet

This leaflet answers some common questions about BENZAC AC.

It does not contain all the information available on this medicine. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. If you have any concerns about using this medicine, ask your doctor or pharmacist.

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Keep this leaflet with your medicine.

You may need to read it again.

What BENZAC AC is used for

BENZAC AC Gel is used as an aid for the treatment of acne.

It contains benzoyl peroxide which

- kills the bacteria on the skin that cause acne
- unplugs blocked pores (blackheads and whiteheads)

BENZAC AC Gel also contains acrylates copolymer beads that absorb excess oils and release glycerol which reduces the risk of irritation.

Before you use BENZAC AC

When you must not use it

Do not use BENZAC AC:

- if you have an allergy to any medicine containing benzoyl peroxide
- if you have an allergy to any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives of the skin

Do not use BENZAC AC if the packaging is torn or shows signs of tampering.

Do not use BENZAC AC if the expiry date (EXP) printed on the pack has passed.

If you use this medicine after the expiry date has passed, it may not work (as well). If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure if you should start using BENZAC AC, talk to your doctor or pharmacist.

Before you start to use it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breast-feeding.

BENZAC AC should only be used by a pregnant woman if clearly needed.

Caution should be exercised when BENZAC AC gel is administered to a breastfeeding woman. BENZAC AC should not be used on the chest in a breastfeeding woman to avoid accidental transfer to the infant.

Your doctor can discuss with you the risks and benefits involved.

BENZAC AC should only be used on the skin.

Using other medicines

Tell your doctor or pharmacist if you are using or taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking using medicine.

How to use BENZAC AC

BENZAC AC is for EXTERNAL USE ONLY.

Always begin treatment with either 2.5% or 5% BENZAC AC. Provided your skin tolerates the lower strength gel, your doctor or pharmacist may recommend continued treatment with the higher strength gel. BENZAC AC is a spot treatment and should only be applied to affected areas.

A mild burning sensation will probably be felt on first application and some reddening and peeling of the skin will occur within a few days. During the first weeks of treatment a sudden increase in peeling will occur in most patients. This is not harmful and will normally subside within a day or two if treatment is temporarily discontinued. If you experience any reaction and if these reactions bother you, use the medication less frequently or discontinue use temporarily or discontinue use altogether.

Benzoyl peroxide may cause swelling and blistering of the skin, if any of these symptoms occur, medication has to be discontinued.

How to use it

Wash and dry your hands before applying the gel.

Unless your doctor or pharmacist has told you otherwise, follow these three steps:

Step 1.

Wash the affected area with a mild skin cleanser and water and pat skin dry.

Step 2.

Apply **a thin film of BENZAC AC to the affected areas once daily**, leaving on the skin for 2 hours then washing it off with water then pat skin dry.

Step 3.

Apply a light **moisturiser** which won't clog pores.

After three days, if no discomfort is felt, **apply BENZAC AC in the evening and leave it on all night.**

After 7 days, if there is no redness or peeling and your skin is still not improving, apply BENZAC AC twice a day morning and night

How long to use it

How long you will need to use BENZAC AC will depend on how quickly your condition improves.

Persevere with your therapy as acne can take time to improve. After you have used it for one month, you should see your doctor or pharmacist again so they can check the improvement in your condition.

If you are not sure how long to use BENZAC AC, talk to your doctor or pharmacist.

If you forget to use it

If you forget to apply it use it again as directed, as soon as you remember.

Do not double the amount used to make up for the application that you missed.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

If you use too much gel, you may find that your skin becomes irritated no more rapid or better results will be obtained and severe irritation might develop. In this case, treatment must be discontinued and appropriate symptomatic therapy should be established.

Wash off as much as you can and when the irritation has gone down; start using it again as directed.

If you swallow it

Immediately telephone your doctor, or Poisons Information Centre (telephone 13 11 26 in Australia, 0800 764766 in New Zealand), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have swallowed BENZAC AC.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention

While you are using BENZAC AC

Things you must do

Tell all doctors and pharmacists who are treating you that you are using BENZAC AC.

If you feel that BENZAC AC is not helping your condition, tell your doctor or pharmacist.

Things to avoid

Avoid contact with the eyes, lips, mouth, angles of the nose, mucous membranes and sensitive areas of the neck. If accidental contact should occur, rinse thoroughly with warm water and pat dry. Contact may cause irritation.

BENZAC AC should not be applied to damaged skin.

Do not use BENZAC AC with any other acne products that are used on the skin unless your doctor or pharmacist has told you that you can, as this may cause your skin to become red and sore.

Avoid excessive exposure to sunlight or other sources of ultra-violet light.

Things you can do

Apply a non-greasy, broad spectrum, high SPF Factor sunscreen when sun protection is needed.

Things to be careful of

Keep use of cosmetics to a minimum and avoid oil based cosmetics which can clog the pores.

Be careful when using BENZAC AC gel because benzoyl peroxide can bleach or discolour clothing, towels or bed linen. Make sure you wash your hands thoroughly after you have used it.

Fair-skinned individuals are more likely to be susceptible to irritation when using BENZAC AC.

Do not use harsh skin cleansers, scrubs, medicated soaps or cosmetic products containing alcohol as these may have an additional drying or irritant effect.

BENZAC AC contains propylene glycol which may cause skin irritation.

Side effects

It is normal in the first weeks to experience a feeling of skin tension or a burning, stinging or itching sensation and a small amount of peeling or reddening of the skin. These effects are usually mild and can be relieved by the use of a moisturising cream or lotion. Alternatively, you may reduce the number of times you apply BENZAC AC to once a day or once every two days until your skin adjusts to the product.

Tell your doctor or pharmacist if excessive swelling, irritation, redness or peeling occurs.

BENZAC AC helps most people with acne, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, sometimes they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following changes to your skin and they worry you:

- Dry skin
- Skin redness
- Peeling of the skin
- Burning sensation of the skin
- Itching of the skin (pruritus)
- Pain of the skin (pain, stinging)
- Skin irritation
- Allergic contact dermatitis

Mostly these are mild and short-lived.

In the event of serious allergic reactions, including application site hypersensitivity, face swelling and anaphylaxis, you may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell or is affecting your skin.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using BENZAC AC

Carefully replace the cap on the tube to avoid spillage or leakage.

Storage

Keep the medicine in a cool dry place where the temperature stays below 25°C.

Keep it where children cannot reach it.

A locked cupboard at least one and-a-half metres above the ground is a good place to store medicines.

Product description**What it looks like**

BENZAC AC gel is a smooth white gel in a plastic tube with a screw top. It is available in a 50g and 60g tube. Not all pack sizes may be available.

BENZAC AC is available in three strengths: 2.5%, 5% or 10% of benzoyl peroxide.

Ingredients

Gel base contains docusate sodium, disodium edentate, poloxamer 182, carbomer 940, propylene glycol, acrylates copolymer, glycerol, silicon dioxide, sodium hydroxide and purified water.

Sponsor

Galderma Australia Pty Ltd
13B Narabang Way
Belrose NSW 2085
Call 1800 800 765 (Australia)

Healthcare Logistics'
58 Richard Pearce Drive
Airport Oaks
Auckland New Zealand
Call 0800 174 104 (New Zealand)

Australian Registration Number:

2.5% AUST R 25270

5.0% AUST R 25271

10% AUST R 25268

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