



BENZAC AC 2.5% Gel

Benzoyl Peroxide

BENZAC AC 5% Gel

Benzoyl Peroxide

BENZAC AC 10% Gel

Benzoyl Peroxide

Read all of this leaflet carefully because you start taking this medicine.

- Keep this leaflet, You may need to read it again.

- If you have any further questions about your illness or your medicine, ask your doctor or pharmacist.

- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Benzac AC is and what it is used for.

2. Before you use Benzac AC.

3. How to use Benzac AC.

4. Possible side effects.

5. How to store Benzac AC.

6. Further information

1. What Benzac AC is and what it is used for.

- Benzac AC contains the active ingredient benzoyl peroxide which attacks the bacteria (germs) known as Propionibacterium acnes, one of the main causes of acne.

- Your doctor or pharmacist has recommended this medicine to treat your acne. Acne appears as blackheads and whiteheads which people often refer to as pimples or spots.

- Acne of the face, chest or back may be treated with this medicine.

2. Before you use Benzac AC.

Do not use Benzac AC if:

• You are allergic (*hypersensitive*) to benzoyl peroxide or any of the other ingredients (listed in Section 6).

Do not use Benzac AC if the above applies to you. If you are not sure, ask your pharmacist or doctor before you use this medicine.

Take special care with Benzac AC.

Talk to your doctor or pharmacist before using Benzac AC.

• Avoid contact with the eyes, mouth, angles of the nose and other mucous surfaces such as the lining of your nose. If accidental contact should occur, rinse thoroughly with warm water.

• Benzac AC should not be applied to damaged skin.

• Benzac AC may cause swelling and blistering of the skin, if any of these symptoms occur, use of the product should be discontinued.

• This product may bleach hair and coloured fabrics including clothing, towels and bed linen. Be careful to avoid contact of the gel with these materials.

• Please make sure that you wash your hands thoroughly after you have used it.

• Caution should be exercised when applying Benzac AC to the neck and other sensitive areas.

• Avoid repeated exposure to sunlight or other sources of UV light (e.g. sun bed).

Using other medicines with Benzac AC.

Please tell your pharmacist or doctor if you are using or have recently used any other medicines. This includes medicines you get without a prescription, such as herbal medicines.

In particular, tell your doctor or pharmacist:

• If you are using other acne treatment. If used at the same time, it may make skin irritation worse.

Pregnancy and breast-feeding

There is only limited information about the safety of Benzac AC in pregnant women.

• Tell your doctor or pharmacist if you are pregnant or planning to become pregnant.

• If you do become pregnant during treatment with Benzac AC tell your doctor.

It is not known whether the ingredients of Benzac AC can pass into breast milk. If you are breast-feeding, you must check with your doctor or pharmacist before you use Benzac AC.

• Don't use BENZAC AC on your breast if you are breast-feeding.

Important information about some of the ingredients of Benzac AC

Benzac AC contains propylene glycol. Propylene glycol may cause skin irritation.

3. How to use Benzac AC.

If this medicine is from your pharmacist or doctor, follow their instructions. Otherwise, follow the instructions below. If you do not understand the instructions or are not sure, ask your pharmacist or doctor.

- Wash the affected area with a mild skin cleanser and water, and gently pat your skin dry.

- Apply the gel in a thin layer once or twice a day to all the affected areas.

- If you have sensitive skin, apply the gel once daily before going to bed.

- Any drying or peeling which may occur to your skin may be reduced if you alter the number of times you apply, i.e. to once a day or once every two days, until your skin adjusts to the product.

• You should try to avoid exposure to strong sunlight while using Benzac AC. If exposure is unavoidable, use a suitable sunscreen lotion and apply Benzac AC in the evening. Remember to wash the affected area before use.

• How long you will have to use Benzac AC will depend on how quickly your condition improves. After you have used it for one month, you should see your doctor or pharmacist again. He can then check the improvement of your condition.

If you forget to use Benzac AC.

• Do not use a double dose to make up for forgotten doses.

• Skip the dose and apply the next dose at the usual time.

If you more Benzac AC than you should or accidentally swallow the gel.

The ingredients of Benzac AC are not expected to be harmful if swallowed in the small amounts normally applied to the face. However, if you do accidentally get a larger amount of Benzac AC in your mouth, rinse immediately with plenty of water.

Contact your doctor or pharmacist for advice.

4. Possible side effects.

Like all medicines, Benzac AC can cause side effects, although not everybody gets them:

Severe allergic reactions:

Signs may include:

• Raised and itchy rash (*hives*)

• Swelling of the face or mouth (*angioedema*), causing difficulty in breathing.

• Collapse.

Contact a doctor immediately if you get these symptoms. Stop using Benzac AC immediately.

Very common side effects:

These may affect more than 1 in 10 people:

• Dry skin.

• Skin redness.

• Peeling of the skin.

• Burning sensation of the skin.

Common side effects:

These may affect up to 1 in 10 people:

• Itching of the skin (*pruritus*).

• Pain of the skin (pain, stinging).

• Skin irritation (irritant contact dermatitis).

Uncommon side effects:

These may affect up to 1 in 100 people:

• Allergic contact dermatitis.

These symptoms are usually reversible if the treatment is reduced in frequency or discontinued.

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.

5. How to store Benzac AC.

• Keep out of the reach and sight of children.

• Benzac AC should be stored below 25°C.

• Do not use Benzac AC after the expiry date which is printed on the tube and carton.

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

6. Further information

What Benzac AC contains

• The active ingredient is benzoyl peroxide. The amount of benzoyl peroxide in your medicine is indicated by the number after the name 'Benzac AC 2.5 contains 2.5% w/w benzoyl peroxide. Benzac AC 5 contains 5% w/w benzoyl peroxide. Benzac AC 10 contains 10% w/w benzoyl peroxide.

• The other ingredients are docusate sodium, disodium edetate, poloxamer 182, carbomer 940, propylene glycol, acrylates copolymer, glycerol, colloidal anhydrous silica, purified water and sodium hydroxide to adjust the pH.

What Benzac AC looks like

Benzac AC is a white gel and comes in 60g tube.

Marketing Authorisation Holder and Manufacturer

Marketing Authorization Holder: Galderma International, Tour Europlaza – La Defense 4, 20, avenue Andre Prothin, 92927 La Defense Cedex – France.

Manufactured by: Laboratories GALDERMA, Z.I.-Montdésir, 74540 Alby-sur-Chéran-France.

- For any further information about this medicinal product, please contact: ME.Regulatory.AEDXB@galderma.com

- This leaflet last reviewed in (06/2018), version number (2).

- To report any side effects:

* Saudi Arabia:

- The National Pharmacovigilance and Drug Safety Centre (NPC)

o Fax: +966-11-205-7662

o Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.

o Toll free phone: 8002490000

o E-mail: npc.drug@sfd.gov.sa

o Website: www.sfd.gov.sa/npc

* Other GCC States:

- Please contact the relevant competent authority.

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed for you.

- Do not repeat the same prescription without consulting your doctor.

- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists