

ACNECIDE® 5%w/w gel

benzoyl peroxide



Package leaflet: Information for the user
Acnecide 5% w/w Gel
Benzoyl Peroxide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

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

1. What Acnecide is and what it is used for

- Acnecide 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. What you need to know before you use Acnecide

Do not use Acnecide if you are:

- Allergic (hypersensitive) to benzoyl peroxide or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include a rash or itching.

Warnings and precautions

Talk to your doctor or pharmacist before using Acnecide.

- 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.
- Acnecide should not be applied to damaged skin.
- Acnecide 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 Acnecide to the neck and other sensitive areas.
- Avoid repeated exposure to sunlight or other sources of UV light (e.g. sun bed)

Other medicines and Acnecide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- You should not use medicines with peeling, irritant and drying effects at the same time as Acnecide.
- Do not use Acnecide 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 very sore.

Pregnancy and breast-feeding

- If you are pregnant or think you may be pregnant or are breast-feeding, do not use this product unless your doctor has told you that you can.
- Avoid using this product if you are breast-feeding unless your doctor has told you otherwise. If your doctor has recommended the use of this product while you are breast-feeding, you must not apply the gel onto your chest, this is to avoid exposure of your child to this product.

Ask your doctor or pharmacist for advice before taking any medicine.

Acnecide contains propylene glycol.

Propylene glycol may cause skin irritation.

3. How to use Acnecide

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

• Acnecide is for EXTERNAL USE ONLY.

- Unless your doctor or pharmacist has told you otherwise,
 - 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 Acnecide. If exposure is unavoidable, use a suitable sunscreen lotion and apply Acnecide in the evening. Remember to wash the affected area before use.
- How long you will have to use Acnecide 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 or she can then check the improvement of your condition.

Galderma Laboratories

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Artwork approved by:

Date:

Signature:

This approval applies to whole text, including barcodes, pre-printed mentions and legal or special labelling constraints. PLEASE CHECK PROOF CAREFULLY TO ENSURE ALL ELEMENTS ARE CORRECT.

If you use more Acnecide than you should or accidentally swallow the gel

- If you should accidentally use too much gel, you may find that your skin becomes irritated. Wash off as much as you can, and when the irritation has gone down, start using it again as directed.
- In the rare event that you accidentally swallow any of this product, seek medical advice.

If you forget to use Acnecide

- Don't worry if you forget to use your 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If your skin becomes severely irritated, or severe redness, itching or peeling of the skin occurs, or you experience face swelling, **discontinue use immediately and consult your doctor or pharmacist.**

Tell your doctor immediately if you develop a severe allergic reaction:

Signs of severe allergic reactions may include:

- Raised and itchy rash (hives)
- Swelling of the face, eyes, lips, tongue or mouth (angioedema), having difficulty in breathing
- Fainting

Acnecide may cause the following side effects:

Very common: may affect more than 1 in 10 people

- Dry skin
- Skin redness
- Peeling of the skin
- Burning sensation of the skin

Common: 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: 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Acnecide

- 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 tube and carton. The expiry date refers to the last day of that month.
- Do not store above 25°C. Do not freeze.
- Store the closed tube away from direct heat.

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 Acnecide contains

The active substance is hydrous benzoyl peroxide equivalent to benzoyl peroxide 5% w/w in an aqueous, non-alcoholic gel base.

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 Acnecide looks like and contents of the pack

Acnecide is a white to off-white gel. It is available in tubes of 15g, 30g and 60g from your pharmacist or on prescription from your doctor.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Galderma (UK) Limited, Meridien House, 69-71 Clarendon Road, Watford, Herts, WD17 1DS, UK (PL 10590/0006)

Manufacturer: Laboratoires Galderma, ZI- Montdésir, 74540 Alby-sur-Chéran, France.

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