

ACNECIDE® Face 5% w/w Gel

Contains 5% Benzoyl Peroxide



Package leaflet: Information for the user Acnecide Face 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 pharmacist or doctor has told you.

- Keep this leaflet. You may need to read it again.
- The product is for **mild acne** which is limited to the **face only**.

- If your acne gets worse while using Acnecide Face Gel or if it does not improve within 12 weeks, it is important that you see your pharmacist or doctor for advice. Under treatment of some forms of acne may sometimes result in scarring. Your pharmacist or doctor will be able to recommend an alternative treatment for your acne.

- The product is not to be used with any other preparation for acne, unless under supervision of a doctor (see section 2, 'other medicines and Acnecide Face Gel').
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your pharmacist or doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Acnecide Face Gel is and what it is used for

- Acnecide Face Gel contains the active ingredient benzoyl peroxide which kills the bacteria (germs) known as Propionibacterium acnes, one of the main causes of acne.
- Acnecide Face Gel is for the treatment of mild acne on the face, in adults and adolescents 12 years and over. Mild acne appears as predominately blackheads and whiteheads and there are few or no spots and pimples and no inflamed spots. Please take a look at the diagrams below showing the different types of acne:



2. What you need to know before you use Acnecide Face Gel

Do not use Acnecide Face Gel 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.
- have any inflamed spots or larger lumps on your face, because you may have more severe acne and you should see your pharmacist or doctor for advice about treatment.
- have scars from past acne spots, usually a shallow dent or deeper pit in the skin, you should see your pharmacist or doctor for advice.
- have any acne on your shoulders, back or chest. Treating acne in these areas can be difficult and you should ask your pharmacist or doctor about how to treat it.

Warnings and precautions

- Talk to your pharmacist or doctor before using Acnecide Face Gel if you are unsure if your spots are acne or not.
- **If you are worried or upset about your acne, even if it is mild, you should consult your pharmacist or doctor for advice. Acne can be associated with increased risk of depression, anxiety, poor self-image and poor self-esteem. If you experience any of these psychological effects, please consult your doctor for professional advice.**
- Avoid contact of the face gel 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 water.
- Acnecide Face Gel should not be applied to damaged skin.
- Acnecide Face Gel may cause swelling and blistering of the skin, if any of these symptoms occur, use of the product should be discontinued and you should see your pharmacist or doctor for advice
- This product may bleach hair and coloured fabrics including clothing, towels and bed linen. Be careful to avoid contact of the face gel with these materials. Please make sure that you wash your hands thoroughly after you have used it.
- Acnecide Face Gel should not be applied to the neck and other sensitive areas of skin (e.g. around the eyes).
- Acnecide Face Gel can cause increased sensitivity to sunlight, therefore excessive exposure to sunlight should be avoided. Sunbeds should not be used whilst using Acnecide Face Gel.

Children and adolescents aged less than 12 years

Acnecide Face Gel should not be used by children less than 12 years of age.

Other medicines and Acnecide Face Gel

Tell your pharmacist or doctor 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 Face Gel.
- Do not use Acnecide Face Gel with other benzoyl peroxide containing products (including other Acnecide products), or any other preparations for acne, unless under supervision of a doctor.

Pregnancy and breast-feeding

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

Driving and using machines

Acnecide Face Gel has no or negligible affect on your ability to drive or use machines.

Acnecide Face Gel contains propylene glycol.

Propylene glycol may cause skin irritation.

3. How to use Acnecide Face Gel

Always use this medicine exactly as described in this leaflet. Check with your pharmacist or doctor if you are not sure. **Benzoyl Peroxide may cause irritation.**

You should therefore start by using this product on alternate days to minimise this risk and then gradually increase the frequency up to twice a day use if tolerated. If you experience any severe skin irritation stop using the product. If this irritation does not improve after stopping, please consult your pharmacist or doctor.

- Acnecide Face Gel is for **EXTERNAL USE ONLY**.

Galderma Laboratories

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Adults and adolescents aged 12 years and over

Unless your pharmacist or doctor 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 to all the affected areas of the face. Avoid contact with sensitive areas such as eyes, mouth, nose lining and neck.
 - When you first use Acnecide Face Gel apply the gel once daily before going to bed. You may feel mild burning and notice slight reddening and peeling of the skin during the first few days. If you have more severe redness, burning, irritation and peeling then you should stop treatment and let your skin go back to normal before restarting treatment.
 - If Acnecide Face Gel does not affect your skin, or you have only mild burning and slight reddening and peeling after 2-3 days of use, you can apply the gel twice a day, in the morning and evening. If this causes more severe skin symptoms (burning, irritation, redness, peeling) then you should go back to using Acnecide Face Gel only once a day. If your skin remains more severely irritated you should stop treatment and let your skin go back to normal before restarting treatment once a day.
 - If you get severe skin irritation at any time whilst using Acnecide Face Gel you should stop the treatment. If your skin does not recover after stopping treatment you should seek a doctor's advice.
 - Using a moisturiser after application can help to reduce any irritation the treatment may cause.
- You should try to avoid exposure to strong sunlight while using Acnecide Face Gel. If exposure is unavoidable, use a suitable sunscreen lotion and apply Acnecide Face Gel in the evening. Remember to wash the affected area before use.
 - How long you will have to use Acnecide Face Gel will depend on how quickly your condition improves.
 - **If your acne gets worse while using Acnecide Face Gel or if it does not improve within 12 weeks, it is important that you see your pharmacist or doctor for advice. Under treatment of some forms of acne may sometimes result in scarring. Your pharmacist or doctor will be able to recommend an alternative treatment for your acne.**
 - If your spots heal but leave a scar for the first time, which is usually a shallow dent or deeper pit in the skin, you should see your pharmacist or doctor for advice. You may require additional or alternative treatment for your acne.
 - Acnecide Face Gel should not be used in adolescents and children under 12 years of age.

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

- Using more than a thin layer of Acnecide Face Gel will not get rid of your acne any quicker, but your skin may become irritated. If your skin becomes irritated, treatment should be stopped and you should contact your pharmacist or doctor
- In the rare event that you accidentally swallow any of this product, seek medical advice.

If you forget to use Acnecide Face Gel

- 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 pharmacist or doctor.

4. Possible side effects

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

STOP using Acnecide Face Gel and tell your doctor immediately if you develop a severe allergic reaction. Signs of severe allergic reaction may include:

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

Acnecide Face Gel 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 (redness, inflammation, bumps, dry and cracked, or a burn-like rash on the skin at the site of exposure).

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

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

Reporting of side effects

If you get any side effects, talk to your pharmacist or doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 Acnecide Face Gel

- 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 Face Gel 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 Face Gel looks like and contents of the pack

Acnecide Face Gel is a white to off-white gel. It is available in tubes of 15 g.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Galderma (UK) Limited, Meridien House, 69-71 Clarendon Road, Watford, Herts, WD17 1DS, UK (PL 10590/0069)

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

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7. General advice for people with acne

- Try not to touch your face too much and do not pick or squeeze your spots as this can make them worse.
- Cleanse your skin and remove make-up with a mild cleanser and water, or an oil-free soap substitute. Scrubbing too hard can irritate the skin and make your acne worse. Remember, poor washing does not cause blackheads.
- Baths and showers should not be too hot as this can strip skin of its natural oils and may make acne worse.
- Skin should always be moisturised following cleansing and after applying any treatments as some products can cause drying and redness of the affected skin.
- If you use make up, choose products that are oil-free or water-based. Products that are labelled as being 'non-comedogenic' (should not cause blackheads or whiteheads) or non-acnegenic (should not cause acne), are less likely to make acne worse.
- If you go out in the sun, use a sunscreen. Choose products labelled as oil-free, water based or non-comedogenic, to avoid clogging pores.
- Shave carefully. If you shave, you can try both electric and safety razors to see which works best. With safety razors, use a sharp blade. Also, it helps to soften your beard with soap and water before putting on shaving cream. Shave lightly and only when you have to.

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