

PACKAGE LEAFLET: INFORMATION FOR THE USER

Acnecide Wash 5% w/w Gel Benzoyl Peroxide

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Acnecide carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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 works in two ways. Firstly, it has an antibacterial effect against the bacteria that cause acne. Secondly, it cleanses the skin by causing the skin to peel.
- Acnecide is used in the treatment of acne. It is used on the face, chest or back for acne, where the skin has a lot of blackheads, spots and pimples.
- Acnecide is only absorbed into the body in very small amounts and has little effect, except on the surface of the skin.

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. Please check by reading the list of ingredients in section 6. If you answer yes, you must inform your doctor before starting treatment.

Please seek immediate medical attention if you experience symptoms of an allergic reaction. Signs or symptoms of a severe allergic reaction may include a rash, with or without itching, swelling of the face, eyelids or lips and difficulty in breathing.

Take special care with Acnecide

- Avoid contact with the eyes, mouth, angles of the nose or other very sensitive areas of the body. If the preparation enters the eye, wash thoroughly with water.

- Acnecide should not be applied to damaged skin.
- 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).
- Avoid contact with any coloured material including hairs and dyed fabrics as it may result in bleaching or discoloration.
- If your condition does not improve or is aggravated discontinue use and consult your doctor or pharmacist.

Using other medicines

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

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

- If you are pregnant or may be pregnant or are breast-feeding, do not use Acnecide unless your doctor has told you that you can.
- Do not apply Acnecide onto your chest, if you are breast feeding.
- Ask your doctor or pharmacist for advice before taking any medicine.

3. How to use Acnecide

Always use Acnecide exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Acnecide is applied to the skin and is for EXTERNAL USE ONLY.

Unless otherwise directed, Acnecide should be applied once or twice daily to cover the affected skin areas. Wet the area to be treated. Place a small amount of the gel on to the hands to wash the affected area. Contact time with the skin should be 1 to 5 minutes followed by thorough rinsing with water and drying. After use, wash hands thoroughly and replace the cap tightly.

Avoid contact with the eyes, mouth, angles of the nose or other very sensitive areas of the body. If the preparation enters the eye, wash thoroughly with water.

If your skin is likely to be exposed to strong sunlight use a suitable sunscreen lotion and apply Acnecide in the evening.

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

- If you apply too much Acnecide, no more rapid or better results will be obtained and severe irritation might develop. In this event, treatment should be stopped and you should contact your doctor.
- In the event that Acnecide is accidentally swallowed, contact your doctor.

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 product, ask your doctor or pharmacist.

4. Possible side effects

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

Acnecide may cause the following side effects:

Very common (occur in more than 1 in 10 patients)

- Dry skin
- Skin reddening
- Skin peeling
- Burning sensation

Common (occur in less than 1 in 10 patients)

- Skin itching
- Skin pain
- Skin irritation

Uncommon (occur in less than 1 in 100 patients)

- Allergic contact reactions

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

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

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 (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

IRELAND: FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.

Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.imb.ie, email:

imbpharmacovigilance@imb.ie.

5. How to store Acnecide

- Keep out of the reach and sight of children.
- Do not use Acnecide after the expiry date which is stated on the tube or outer carton. The expiry date refers to the last
- day of that month.
- Do not store above 25°C.

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. Contents of the pack and other information

What Acnecide contains

The active substance is hydrous benzoyl peroxide equivalent to 5% w/w benzoyl peroxide in a cleansing gel. The other ingredients are acrylates copolymer, glycerol, carbomer 940, sodium C14-C16 olefin sulfonate, sodium hydroxide, and purified water.

What Acnecide looks like and contents of the pack

Acnecide is a white to off-white gel which is available in a 50g and 100g tube, from your pharmacist. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Galderma International, Tour Europlaza, 20, Avenue André Prothin, La Défense 4, 92927 Paris, La Défense, CEDEX, France (PA22743/001/002)

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