# Package leaflet: Information for the user Acnecide Wash 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 Wash is and what it is used for
- 2. What you need to know before you use Acnecide Wash
- 3. How to use Acnecide Wash
- 4. Possible side effects
- 5. How to store Acnecide Wash
- 6. Contents of the pack and other information

#### 1. What Acnecide Wash is and what it is used for

- Acnecide Wash contains the active ingredient benzoyl peroxide which attacks the bacteria (germs) known as Propionibacterium acnes, one of the main causes of acne.
- Acnecide Wash is used in the treatment of acne. It is used on the face, chest or back where the skin has a lot of blackheads, spots, and pimples.
- Acnecide Wash 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 Wash 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 Wash

### Do not use Acnecide Wash 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 Wash

Talk to your doctor or pharmacist before using Acnecide Wash.

- 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 Wash should not be applied to damaged skin.
- Caution should be exercised when applying Acnecide Wash 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 hair and dyed fabrics as it may result in bleaching or discoloration.
- If your condition does not improve or gets worse discontinue use and consult your doctor or pharmacist.

### Using other medicines

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 Wash.

## Pregnancy and breast-feeding

- If you are pregnant or may be pregnant or are breast-feeding, do not use Acnecide Wash unless your doctor has told you that you can.
- Do not apply Acnecide Wash onto your chest, if you are breast feeding.

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

## 3. How to use Acnecide Wash

- 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 Wash is applied to the skin and is for EXTERNAL USE ONLY.
- Unless your doctor or pharmacist has told you otherwise:
- Acnecide Wash should be used once or twice daily to cover the affected skin areas.
- Wet the area to be treated.
- Wash hands before use and place a small amount of Acnecide Wash 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 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. In the event that Acnecide Wash is accidentally swallowed, contact your doctor.

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

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

• If you use too much Acnecide Wash you will not get rid of your acne any quicker, but your skin may become irritated. If this occurs, treatment should be stopped and you should contact your doctor.

In the event that Acnecide Wash is accidentally swallowed, contact your doctor.

### If you forget to use Acnecide Wash

Don't worry if you forget to use your wash 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, Acnecide Wash can cause side effects, although not everybody gets them. Acnecide Wash 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

#### 5. How to store Acnecide Wash

- 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 outer carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C.

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 to protect the environment.

# 6. Contents of the pack and other information What Acnecide Wash contains

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

## What Acnecide Wash looks like and contents of the pack

Acnecide Wash 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

Manufacturer: Laboratories Galderma Zl-Montdesir 74540 Alby-sur-Cheran France.

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