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Certification Statement

We certify that the final electronic form of this material is in accordance with the regulations set forth by the health authority for the country of this document, and is a fair and truthful presentation of the facts about the product.

Role	Signature
Nadia Kissoum (nadia.kissoum@galderma.com), Launch Coordinator, on behalf of Florence Chereau - Approve (florence.chereau@galderma.com)	Meaning: As the Operation Approver, I approve this document for use. Date: 01-Aug-2023 13:31:04 GMT+0000

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 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 within four weeks.
- 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 contains the active substance benzoyl peroxide which attacks the bacteria (germs) known as Cutibacterium 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. 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 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.
- 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).
- Fair-skinned individuals are more likely to be susceptible to irritation when using Acnecide.

Using 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.

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 or think you may be pregnant or are breast-feeding, do not use this product 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.

Important information about some of the ingredients in Acnecide

- This medicine contains 40 mg of propylene glycol (E1520) per gram, which is equivalent to 4.0 %w/w. It may cause skin irritation.

3. How to use Acnecide

Adults and children

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

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LABORATOIRES GALDERMA - Z.I. Galderma - 74540 ALBY-SUR-CHÉРАН - FRANCE	
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	DIELINES

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 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.

While you are using Acnecide

- It is normal in the first weeks to experience a feeling of skin tension or a burning, stinging or itching sensation, and a small amount of peeling or reddening of the skin. These effects are usually mild and can be relieved by the use of a moisturising cream. They will go when treatment stops or the gel is applied less often.
- If any of the side effects gets serious, or if 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.

HPRA Pharmacovigilance, website: www.hpra.ie

5. How to store Acnecide

- Keep out of the sight and reach of children.
- Do not use Acnecide 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.

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 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 (E1520), 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 30g, 40g 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 International,
Tour Europlaza,
20 Avenue André Prothin,
La Défense 4,
92927 Paris,
La Défense,
CEDEX,
France
PA22743/001/001
Tel: +44 300 3035674
E-mail: medinfo.uk@galderma.com

Manufacturer:

Laboratoires Galderma
ZI-Montdésir
74540 Alby-sur-Chéran
France

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