



Acnecide Face 5% w/w Gel & Acnecide Face Wash 5% w/w Gel (benzoyl peroxide)

Public Consultation

Proposal to make available from general sales outlets

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK government agency responsible for regulating medicines and medical devices. We continually review the safety of medicines and vaccines in the UK and inform healthcare professionals and the public of the latest updates through several means, including public reclassification reports. Suspected side-effects to any drug or vaccine can be reported to MHRA by both healthcare professionals and members of the public via the Yellow Card Scheme (<http://www.mhra.gov.uk/yellowcard>)

Ref: **ARM 98**

Acnecide Face 5% w/w Gel & Acnecide Face Wash 5% w/w Gel (benzoyl peroxide)

Proposal to make available from general sales outlets

We want to know what you think

- Acnecide Face 5% w/w Gel and Acnecide Face Wash 5% w/w Gel are preparations (face gel & face wash) containing benzoyl peroxide intended for use on the face.
- Acnecide Face 5% w/w Gel and Acnecide Face Wash 5% w/w Gel are for the treatment of mild acne affecting the face in adults and adolescents aged 12 years and over.
- Acnecide products (Acnecide 5% w/w Gel and Acnecide Wash 5% w/w Gel) are also currently licensed as pharmacy (P) medicines.
- We propose to make Acnecide 'Face' products available in general sales (non-pharmacy) outlets with more limited conditions of use than the current pharmacy (P) products.
- The Commission on Human Medicines (CHM)¹ has advised that Acnecide 'Face' products can be available as General Sale List (GSL) medicines.
- We want to know what you think about this change.

Please tell us your views – please use the form at the end of this document.

The deadline for comments is **30 May 2019**.

In this document there is:

- A summary of the proposed change and the background
- A copy of the patient information leaflets and labels proposed if the change goes ahead
- A form for your response

The full names of these medicines are 'Acnecide Face 5% w/w Gel' and 'Acnecide Face Wash 5% w/w Gel' – in this document, we will call them 'Acnecide Face Gel' and 'Acnecide Face Wash'.

¹The Commission on Human Medicines (CHM) is an advisory non-departmental public body, sponsored by the Department of Health that advises ministers on the safety, efficacy and quality of medicinal products. The CHM's views are sought on reclassifications when more complex or new reclassifications of medicines are being proposed.

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Product details:

Product names: Acnecide Face 5% w/w Gel & Acnecide Face Wash 5% w/w Gel

Active substance: Benzoyl peroxide

Licence holder: Galderma (UK) Limited

Route of sale/supply: Current - Pharmacy medicine (P); Proposed - General Sale List (GSL)

Indication: For the treatment of mild acne affecting the face, when comedones (blackheads and whiteheads) predominate and there are few or no papules or pustules (acne spots and pimples) and no inflamed spots, in adults and adolescents aged 12 years and over.

Marketing Authorisation Numbers: PL 10590/0069 & 10590/0070

Consultation is open from: 09 May 2019 – 30 May 2019

Reference: ARM 98

Contact: reclassification@mhra.gov.uk

1. Background on deciding where medicines are available

The role of MHRA

MHRA regulates medicines and medical devices in the UK, on behalf of the UK Licensing Authority. This means that MHRA decides whether medicines are available:

- on prescription only - 'prescription only medicine' (POM)
- bought from pharmacies - 'pharmacy medicine' (P)
- bought from other shops - 'general sales list medicine' (GSL)

What is re-classification of a medicine?

Making a change on where a medicine is available is called 'reclassification'. This is sometimes referred to as 'switching'. To decide on this change, MHRA may:

- take advice from the Commission on Human Medicines and its Expert Advisory Groups
- take advice from a group of health professionals and representatives of people affected by the classification change ('stakeholder group')
- run a public consultation

To be reclassified from P to GSL, it must be demonstrated that the medicine may be supplied with reasonable safety in outlets other than in pharmacies. 'Reasonable safety' is defined as 'Where the hazard to health, risk of misuse and need for special precautions in handling of the medicine are small, and where the wider sale would be a convenience to the purchaser'.

What evidence is needed?

A company or organisation can ask MHRA for a medicine to be available as a pharmacy medicine or a general sale medicine. To do this, they need to get together evidence to show that the medicine

- a) is likely to be used appropriately, and
- b) with relatively little danger to the public.

This evidence needs to focus on the risk to the public. This includes evidence on the possible abuse or misuse of the medicine. The evidence may include:

- clinical studies
- evidence showing acceptable level of side effects
- advice of experts
- views of relevant health professionals and their professional bodies
- views of relevant public associations and individuals with an interest in the medicine under consideration.

Who makes the final decision?

The final decision on whether to approve a change is made by the MHRA, on behalf of the UK Licensing Authority.

2. About Acnecide Face Gel & Acnecide Face Wash

Acnecide Face Gel and Acnecide Face Wash are for the treatment of mild acne affecting the face in adults and adolescents aged 12 years and over.

Either product is initially applied once daily to the face at bedtime; after 2-3 days if well tolerated, the product may be used twice daily, in the morning and evening. For the face gel, a thin layer is applied to the skin. For the face wash, the product should remain on the skin for 1-2 minutes, before thorough rinsing with water.

If the acne gets worse while using Acnecide Face Gel/Acnecide Face Wash or if it does not improve within 12 weeks, the patient should seek the advice of a pharmacist or doctor who will be able to recommend alternative treatment for their acne.

The CHM has advised that these products can be made available as General Sale List (GSL) medicines. This report outlines the background to this decision. Please tell us your views by using the response form at the end of this document (Annex 1). The deadline for comments is **30 May 2019**.

The patient information leaflets, labels and summaries of product characteristics² are provided in Annex 2, 3 and 4.

What is in Acnecide Face Gel & Acnecide Face Wash?

Acnecide Face Gel and Acnecide Face Wash are both gels, one intended to be left on the face and the other intended to be used as a wash, kept on the face for 1-2 minutes before being rinsed off with water. They both contain 5% w/w of the active ingredient benzoyl peroxide.

Products currently available in general sales outlets for topical treatment (application to the skin) of spots or acne contain active ingredients such as nicotinamide, chlorhexidine gluconate, and zinc oxide. Traditional herbal registrations³ are available containing tea tree oil.

Acnecide Face Gel and Acnecide Face Wash would be the first products containing benzoyl peroxide to be available as GSL medicines.

²A Summary of Product Characteristics (SmPC) is a legal document describing a medicine's properties and how it can be used. SmPCs are available [online](#) via the MHRA.

³A Traditional Herbal Registration (THR) is a product authorised in the UK under the simplified registration scheme for Traditional Herbal Medicinal Products. Such products are identified by a THR number.

3. Proposal to make Acnecide Face Gel & Acnecide Face Wash available as General Sale List medicines

Who has made the proposal?

The marketing authorisation holder (MAH)⁴ for Acnecide Face Gel and Acnecide Face Wash (Galderma UK Limited) has applied to make these products available through general sales outlets.

In addition to Acnecide Face Gel and Acnecide Face Wash, the MAH currently has marketing authorisations for Acnecide 5% w/w Gel and Acnecide Wash 5% w/w Gel with pharmacy (P) legal status which they intend to maintain, in addition to the proposed GSL products. These pharmacy (P) products are distinguishable from the GSL products primarily by having broader conditions of use (may be used for more severe acne on any part of the body affected) and by their product names.

Proposed terms of reclassification

What are the details of this change?

The application proposes to make Acnecide Face Gel and Acnecide Face Wash available through general sales outlets for:

- topical use (application to the skin)
- adults and adolescents aged 12 years of age and over
- treatment of mild acne affecting the face, when comedones (blackheads and whiteheads) predominate and there are few or no papules or pustules (acne spots and pimples) and no inflamed spots
- initial application once daily at bedtime; after 2-3 days, if well tolerated, frequency of application may be increased to twice daily, in the morning and evening
- the face gel, applied as a thin layer; persons with a sensitive skin should apply once daily before going to bed
- the face wash contact time with the skin should be 1-2 minutes, before thorough rinsing with water

If acne gets worse or it does not improve within 12 weeks, advice should be sought from a pharmacist or doctor.

Acnecide Face Gel will be available in packs of 15g of gel and Acnecide Face Wash in packs of 50g of gel.

⁴ A Marketing Authorisation Holder (MAH) is the company with legal authorisation to make the medicine available to patients.

4. How was the proposal assessed for Acnecide Face Gel and Acnecide Face Wash being available as General Sale List medicines?

The proposal for Acnecide Face Gel and Acnecide Face Wash is for reclassification from pharmacy (P) to GSL. To be reclassified from P to GSL it must be demonstrated that the medicine(s) meet the GSL criterion, which is set out in the Human Medicines Regulations 2012, regulation 62(5). This criterion is as follows:

‘GSL may be appropriate for medicines which can, with reasonable safety, be sold or supplied otherwise than by or under supervision of a pharmacist.’

‘Reasonable safety’ is defined as ‘where the hazard to health and risk of misuse and need for special precautions in handling are small, and wider sale would be a convenience to the purchaser.’

Assessment of suitability for availability in general sales outlets

A GSL medicine may be sold in general sales outlets in the absence of healthcare professional advice. It is important therefore, that a GSL medicine may be safely sold or supplied without need of a consultation with a doctor or pharmacist.

Hazard to health

The safety of benzoyl peroxide, the active ingredient in Acnecide Face Gel and Acnecide Face Wash is well established. It has been prescribed for topical treatment of acne since the 1960’s; products containing this active ingredient are available in 70 countries worldwide. In the UK, Acnecide 5% w/w Gel was approved as a pharmacy (P) medicine in 1992 and Acnecide Wash 5% w/w Gel as a pharmacy medicine in 2002.

The majority of adverse effects (side effects) reported for Acnecide Gel and Acnecide Face products are skin reactions including very commonly (affecting 1 in 10 or more of patients) dryness, redness, peeling and burning sensation and commonly (affecting 1 in 100 or more, but fewer than 1 in 10 patients) itchiness, pain, stinging and irritation. Less commonly, allergic contact dermatitis (development of allergy due to contact of the skin with the product) may occur.

The proposed instructions for using Acnecide Face Gel and Acnecide Face Wash as a GSL medicine take account of the irritant effects that benzoyl peroxide has on the skin. The proposed instructions are to start using the Face Gel or Face Wash once daily increasing to twice daily if irritation can be tolerated. If excessive irritation occurs, the patient is advised to reduce use to once daily or on alternative days or temporarily stopping application until the skin recovers. If severe irritation occurs, the patient is advised to stop use of the product altogether. If skin does not recover after stopping use, the patient is advised to consult their doctor.

Hypersensitivity reactions and anaphylactic reactions (severe allergic reactions) may occur with use of Acnecide preparations. Such reactions are idiosyncratic in their nature (occur rarely and unpredictably amongst the patient population) and are no more likely to occur in the GSL setting than with the current 'Acnecide' preparations available from pharmacies. The patient information leaflets for Acnecide Face Gel and Acnecide Face Wash advise the patient to seek immediate medical attention if they experience symptoms of severe allergic reaction (raised itchy rash, swelling of the face, eyes, lips, tongue or mouth, difficulty breathing).

Effects on skin colour known as pigmentation disorders, for example, areas of darkened skin (hyperpigmentation) or areas of lightened skin (hypopigmentation) have been identified as possible safety signals (information on new or known adverse events that are potentially caused by a medicine) requiring closer monitoring for 'Acnecide' products. It is not clear whether such disorders are due to the active ingredient (benzoyl peroxide) or due to acne itself.

A risk associated with treatment of acne in the GSL setting is that of delay in seeking professional advice and more appropriate treatment when necessary. This may be the case when acne is more widespread than on the face only or is moderate to severe, in which case Acnecide Face Gel and Acnecide Face Wash would not be appropriate. There may also be delay in receiving more appropriate treatment where the patient starts treatment for their mild acne on the face with Acnecide Face Gel or Acnecide Face Wash, but their acne does not improve or is worsening.

It is essential for the GSL setting therefore that the patient is:

- able to identify whether their acne is suitable for treatment with Acnecide Face Gel or Acnecide Face Wash; therefore, be able to distinguish mild acne from moderate to severe acne
- given clear information about what to do if the product is not effective
- given clear information about the importance of seeking professional advice in cases where acne may be progressing, since under-treatment of certain forms of acne may result in scarring

The risk of using the products for more severe or widespread acne or delay in receiving more appropriate treatment where required, is managed in the patient information for Acnecide Face Gel and Acnecide Face Wash, which includes the following:

Patient information leaflet (PIL)

- statement that the product is suitable for mild acne which is limited to the face only
- clinical images of mild, moderate and severe acne to help the patient distinguish between these forms of acne
- detailed and prominent (emboldened) warning 'If your acne gets worse while using Acnecide Face Gel/ Acnecide Face Wash or if it does not improve within 12 weeks, it is important that you see your pharmacist or doctor for advice. Undertreatment 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.'

Label (outer carton)

- an image of mild acne (consistent with that in the PIL)
- a statement 'For the treatment of mild acne of the face'
- a warning 'If your acne gets worse while using Acnecide Face Gel/ Acnecide Face Wash or if it does not improve within 12 weeks, it is important that you see your pharmacist or doctor for advice. Undertreatment 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 proposed duration of treatment of 12 weeks during which to assess if Acnecide Face Gel or Acnecide Face Wash are having the desired effect for the patient is considered acceptable. In general, most treatments for acne take two to four months to produce their maximum effect. As noted above, the patient information provides advice about what to do if acne is not responding to treatment or if it is worsening.

The proposed pack sizes of 15g for the face gel and 50g for the face wash are suitable and in line with the proposed method of application to the face and initial treatment period of 12 weeks.

Risk of misuse

Incorrect use

There is little risk of Acnecide Face Gel and Acnecide Face Wash being used incorrectly. The proposed instructions for using the products as GSL medicines take account of the irritant effects that benzoyl peroxide has on the skin, advising stepwise increase in application from once to twice daily. If excessive irritation of the skin occurs, reducing application to once daily or on alternative days is recommended. Excessive use of the products in an attempt to improve efficacy will increase irritant effects that benzoyl peroxide has on the skin, including peeling and redness.

Masking a more sinister condition

There is little risk of a more sinister condition being masked as a result of using these products. Acne is a well-recognised condition and medicinal products are already available as GSL to treat it.

Abuse/addiction potential

The active ingredient benzoyl peroxide is not considered to be a compound associated with abuse or addiction potential. There is no known illicit use of this substance. It is intended to be applied to the skin for local action only, its absorption from the skin into the body is low and it does not accumulate in body tissues.

Special precautions in handling

There are no special handling requirements for Acnecide Face Gel and Acnecide Face Wash that would prevent their availability as GSL medicines.

Role of the pharmacist

The proposed condition (mild acne affecting the face) for which Acnecide Face Gel/Acnecide Face Wash are intended to be used, is one which is already being treated by patients in the GSL setting, in absence of healthcare professional advice. Acne is a well-recognised condition, experienced in varying degrees of severity, by a majority of the population during their teens.

Use of Acnecide Face Gel/Acnecide Face Wash in the GSL setting is limited to mild acne affecting the face. To address concerns regarding worsening of acne and potential delay in seeking more appropriate treatment, as a risk minimisation measure, the product information gives the patient relevant precautions, warnings and advice (see 'Hazard to Health' above).

Convenience to the purchaser

Availability of Acnecide Face Gel and Acnecide Face Wash under the conditions proposed would provide additional choice for the patient in the GSL setting for treatment of mild acne affecting the face.

5. Further details on the application

Risk Management Plan

The application contains a risk management plan (RMP) which was required when the product was first authorised. The RMP contains the following:

- the known safety profile of the medicine, including any important identified and potential risks
- what is not known about the safety profile ('missing information')
- how the safety profile will be monitored after the medicine is licensed, including any plans for further studies to actively gain more knowledge about the safety of the medicine ('additional pharmacovigilance activities')
- how any important risks will be prevented or minimised in patients ('risk minimisation measures') and how the usefulness and effectiveness of the risk minimisation measures will be assessed

The RMP for Acnecide Face Gel and Acnecide Face Wash has identified the main risks associated with the products if classified as GSL and proposes how these will be managed. Close monitoring of serious allergic reactions and pigmentation disorders (see section 4 'Hazard to Health' above) are proposed. Otherwise, routine pharmacovigilance (monitoring and reporting of adverse events for a medicine, for which there are no special safety concerns) and risk minimisation via the product information (SmPC, labelling and patient information leaflet) are proposed for these products in the GSL setting.

Label and leaflet

The patient information leaflets and labels are provided in Annex 2 and 3.

Summary of Product Characteristics

The Summaries of Product Characteristics are provided in Annex 4. These documents are descriptions of the properties of Acnecide Face Gel and Acnecide Face Wash and the conditions attached to their use. They are used as references by healthcare professionals.

6. Advice from the Commission on Human Medicines

The Commission on Human Medicines has advised that Acnecide Face Gel and Acnecide Face Wash can be available as GSL medicines. Views on the use of these medicines for the treatment of mild acne affecting the face in people aged 12 years of age and over were also sought at a meeting of the Gastroenterology, Rheumatology, Immunology and Dermatology Expert Advisory Group (GRID EAG)⁵. The views of the GRID EAG were taken into consideration by CHM when they advised on the reclassification application.

7. What do you think?

- Acnecide Face 5% w/w Gel and Acnecide Face Wash 5% w/w Gel are preparations (face gel & face wash) containing benzoyl peroxide intended for application to the face.
- Acnecide Face 5% w/w Gel and Acnecide Face Wash 5% w/w Gel are for the treatment of mild acne affecting the face in adults and adolescents aged 12 years and over.
- Acnecide products (Acnecide 5% w/w Gel and Acnecide Wash 5% w/w Gel) are also currently licensed as pharmacy (P) medicines.
- We propose to make Acnecide 'Face' products available in general sales (non-pharmacy) outlets with more limited conditions of use than the current pharmacy (P) products.
- The Commission on Human Medicines has advised that Acnecide 'Face' products can be available as General Sale List (GSL) medicines.
- We want to know what you think about this change.

Please tell us your views using the form on the next page in Annex 1. The deadline for comments is 30 May 2019.

⁵ An Expert Advisory Group (EAG) supports the work of the CHM in particular area(s) of medicine. One of the areas which the GRID EAG has expertise in is dermatology.

ANNEX 1

Response document for MHRA public consultation on the proposal to make Acnecide Face Gel and Acnecide Face Wash available from general sales outlets without prescription

Ref: ARM 98

Your details

Name:

Position (if applicable):

Organisation (if applicable):

Email:

1. Do you consider that Acnecide Face Gel and Acnecide Face Wash should be available as General Sale List (GSL) medicines?

Yes ☐

No ☐

Not sure ☐

Please provide any comments or evidence to support your response:

2. Do you have any specific comments on the leaflets or the labels provided in the public reclassification report for Acnecide Face Gel and Acnecide Face Wash?

3. Do you have any other comments on the reclassification?

4. The MHRA may publish consultation responses. Do you want your response to remain confidential?

Yes ☐

Partially* ☐

No ☐

*If partially, please indicate which parts you wish to remain confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete.

Responses can be continued onto a separate page if required. This form should be returned by email (reclassification@mhra.gov.uk) to arrive by **30 May 2019**. Contributions received after that date cannot be included in the exercise.

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 doctor or pharmacist 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 doctor or pharmacist. 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 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 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 doctor or pharmacist 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 doctor or pharmacist for 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.
- 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 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 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 doctor or pharmacist 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 doctor or pharmacist 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 doctor or pharmacist if you are not sure.

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

Adults and adolescents aged 12 years and over

- 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 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 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 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 doctor or pharmacist.

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

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 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 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 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.

This leaflet was last revised in 03/2019

7. General advice for people with acne

- Try not 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.

TUBE PLASTIQUE ø19x90
PLAN MT.09.DRA.0003.R01


5% Benzoyl Peroxide

15g Gel

For the treatment of mild acne of the face

PLEASE READ THE ENCLOSED LEAFLET BEFORE USE.

DIRECTIONS: After washing with a mild cleanser and water, apply Acnecide Face Gel 5% on your dried skin once or twice a day to the affected area of the face. May bleach hair and dyed fabrics.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN. DO NOT STORE ABOVE 25 °C. DO NOT FREEZE. FOR APPLICATION TO THE FACE ONLY.

WARNING: AVOID CONTACT WITH THE EYES, MOUTH, ANGLES OF THE NOSE AND OTHER SENSITIVE AREAS OR DAMAGED SKIN.

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

CONTAINS: Hydrous Benzoyl Peroxide equivalent to Benzoyl Peroxide 5% w/w, docusate sodium, disodium edetate, poloxamer 182, carbomer 940, propylene glycol, acrylates copolymer, glycerol, colloidal anhydrous silica, sodium hydroxide and purified water.

PL 10590/0069  GALDERMA

XXXXXX-X Batch No. / Exp. ▶



ACNECIDE® Face 5% w/w Gel

5% Benzoyl Peroxide

15g Gel

For the treatment of mild acne of the face

ACNECIDE® Face 5% w/w Gel

5% Benzoyl Peroxide

15g Gel

For the treatment of mild acne of the face

FIGHTS
THE
BACTERIA
THAT CAUSE
SPOTS

Face Gel

Please read the enclosed leaflet before use

- Do not use with other acne treatments and benzoyl peroxide products unless advised by your doctor.
- 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 you are pregnant or breastfeeding, consult your doctor or pharmacist before using any medicines.
- May bleach hair and dyed fabrics.

FOR APPLICATION TO THE FACE ONLY

BARCODE

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN. DO NOT STORE ABOVE 25°C. DO NOT FREEZE.

CONTAINS: Hydrous Benzoyl Peroxide equivalent to Benzoyl peroxide 5% w/w, docusate sodium, disodium edetate, poloxamer 182, carbomer 940, propylene glycol, acrylates copolymer, glycerol, Colloidal anhydrous silica, sodium hydroxide and purified water.

Galderma (UK) Limited

Meridian House, 69-71 Clarendon Road,
Watford, Herts. WD17 1DS, UK
PL 10590/0069



the eyes, mouth, nose lining and neck.
affected area of the face, but avoiding sensitive areas such as
Face Gel 5% on your dried skin once or twice daily to the
After washing with a mild cleanser and water, apply Acnecide
Adults and adolescents aged 12 years and over.

How to use Acnecide Face Gel 5%?



- Have an allergy to any of the ingredients displayed on this pack.
- Have acne on other parts of your body such as shoulders back or chest.
- Have moderate acne with some inflamed red spots or pimples to severe acne with large bumps, many inflamed spots or previous scarring from acne of the face.

Do not use Acnecide Face Gel 5% if you:



- You are over the age of 12 years.
- You have mild acne on the face.
- Mild acne appears as predominately blackheads and whiteheads and there are few or no spots and pimples and no inflamed spots.

Acnecide Face Gel 5% is suitable if:



Acnecide Face Gel 5% contains the active ingredient benzoyl peroxide, which kills the bacteria (germs) known as Propionibacterium acne, one of the main causes of acne.

How Acnecide Face Gel 5% works on acne spots:



ACNECIDE®
5% Benzoyl Peroxide

15g Gel

Face 5% w/w Gel
For the treatment of mild
acne of the face

Face Gel

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Acnecide Face 5% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrous benzoyl peroxide equivalent to Benzoyl Peroxide 5% w/w

Excipient with known effect: Propylene Glycol 4.0 % w/w

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel

White to off-white, smooth gel

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Topical therapy for the treatment of mild acne affecting the face, when comedones (blackheads and whiteheads) predominate, and there are few or no papules and pustules (acne spots and pimples) and no inflamed spots.

Acnecide Face Gel is indicated in adults and adolescents aged 12 years and over.

4.2 Posology and method of administration

Posology:

Adults and adolescents aged 12 years and over

Before each application, the skin should be cleaned and dried carefully. When first used, apply in a thin layer once daily to the acne-affected areas before going to bed. After 2-3 days, if the treatment is well tolerated, the frequency of application can be increased to twice daily, in the morning and evening. Persons with sensitive skin should apply the gel once daily before going to bed. The extent of any drying or peeling may be adjusted by modifying the dosage schedule (see section 4.4).

Paediatric population:

The safety and efficacy of Acnecide Face Gel in children aged less than 12 years have not been established. No data are available.

Method of administration:

For topical use only

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

For external use only.

This product is not suitable for individuals with severe acne (characterised by large numbers of inflamed spots on the face or the presence of nodules and cysts),

moderate acne (characterised by papules and pustules) or previous scarring from acne, who should seek treatment advice from a doctor.

Individuals with extensive acne lesions affecting other areas (e.g. the chest shoulders and back), which they want to treat, should consult their pharmacist or doctor. These lesions are often more difficult to treat and topical treatments may not be appropriate if they are widespread.

Individuals with mild acne that are particularly concerned by their condition should consult their doctor.

Acnecide Face Gel may cause swelling and blistering of the skin, if any of these symptoms occur, medication has to be discontinued.

A mild burning sensation will probably be felt on first application and some reddening and peeling of the skin will occur within a few days. During the first weeks of treatment a sudden increase in peeling will occur in most people. This is not harmful and will normally subside within a day or two if treatment is temporarily discontinued. Adjunctive use of moisturizers can help to limit the potential for skin irritation.

If severe irritation occurs, individuals should temporarily discontinue use until the irritation subsides. If treatment is restarted, the product should be applied less frequently (i.e. once a day instead of twice daily or alternate days instead of once a day). If severe irritation occurs again after treatment is restarted, discontinue use altogether.

Excessive application will not improve efficacy, but may increase the risk of skin irritation.

In the event of scarring following initial treatment with Acnecide Face Gel, treatment should be discontinued and advice should be sought from a doctor.

Benzoyl peroxide gel should not come into contact with the eyes, mouth, angles of the nose or mucous membranes. If the preparation enters the eye, wash thoroughly with water. Acnecide Face Gel should not be applied to the neck and other sensitive areas (around the eyes and mouth, angles of the nose and mucous membranes).

As Acnecide Face Gel may cause increased sensitivity to sunlight, sunlamps should not be used and deliberate or prolonged exposure to sunlight or UV radiation should be avoided. When strong sunlight cannot be avoided, individuals should use a sunscreen product and wear protective clothing.

Contact with any coloured material including hair and dyed fabrics may result in bleaching or discoloration.

Due to the risk of sensitisation, benzoyl peroxide gel should not be applied on damaged skin.

Acnecide Face Gel should not be used in conjunction with other benzoyl peroxide preparations (including other Acnecide products), nor with any other topical or systemic treatment(s) for acne except under medical supervision.

Individuals should cease use and seek medical advice if their condition deteriorates despite therapy, or in cases of a lack of response after use for 12 weeks.

Acnecide Face Gel contains propylene glycol which may cause skin irritation.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed; however, drugs with desquamative, irritant and drying effects should not be used concurrently with Acnecide Face Gel.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is no safety concern relating to the effects of cutaneously applied benzoyl peroxide on reproductive function, fertility, teratogenicity, embryotoxicity or peri- and post-natal development from animal data. In widespread clinical use for the cutaneous treatment of acne vulgaris, at concentrations up to 10% w/w for several decades, benzoyl peroxide has never been associated with such effects. Acnecide Face Gel should only be used by a pregnant woman under medical supervision

Breast-feeding

It is unknown whether benzoyl peroxide/metabolites are excreted in human milk. A risk to the new-borns/infants cannot be excluded and the preparation should not be applied on the chest to avoid accidental transfer to the infant. Acnecide Face Gel should only be used by a nursing woman under medical supervision.

4.7 Effects on ability to drive and use machines

Acnecide Face Gel has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The adverse reactions resulting from clinical trials are all skin disorders. They are reversible when treatment is reduced in frequency or discontinued.

The following categories are used to indicate the frequency of occurrence of adverse effects:

Very common ($\geq 1/10$)

Common ($\geq 1/100$ to $< 1/10$)

Uncommon ($\geq 1/1,000$ to $< 1/100$)

Rare ($\geq 1/10,000$ to $< 1/1,000$)

Very rare ($< 1/10,000$)

Unknown (Frequency not assessable based on the available data)

They are presented in the table below:

Skin and subcutaneous tissue disorders	Very common ($\geq 1/10$)	Dry skin Erythema Skin exfoliation (peeling) Skin burning sensation
	Common ($\geq 1/100$ to $< 1/10$)	Pruritus Pain of skin (pain, stinging), Skin irritation (irritant contact dermatitis)
	Uncommon ($\geq 1/1,000$ to $< 1/100$)	Allergic contact dermatitis

Swelling face and allergic reactions, including application site hypersensitivity and anaphylaxis (not known frequency) have been reported during post-marketing surveillance.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal

product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Acnecide Face Gel is a preparation indicated for topical treatment only. If the medication is applied excessively, no more rapid or better results will be obtained and severe irritation might develop. In this event, treatment must be discontinued and appropriate symptomatic therapy, including the use of moisturizers, should be instituted.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-acne preparations for topical use, ATC Code: D10AE01

Benzoyl peroxide is an established and effective keratolytic agent with antibacterial properties. It has been shown to be effective in reducing the local population of *Propionibacterium* acnes leading to a reduction in the production of irritant fatty acids in the sebaceous glands.

5.2 Pharmacokinetic properties

The percutaneous penetration of benzoyl peroxide in rat, rabbit, monkey and man is low. The majority of the penetrated benzoyl peroxide is converted into benzoic acid which after absorption into the systemic circulation is rapidly eliminated by the kidney. There is no evidence for any tissue accumulation.

5.3 Preclinical safety data

In animal studies by the cutaneous route, benzoyl peroxide is associated with a minimal to moderate skin irritation potential including erythema and oedema. Phototoxic and photoallergic reactions have been reported for benzoyl peroxide therapy.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Docusate sodium
Disodium edetate
Poloxamer 182
Carbomer 940
Propylene glycol
Acrylates copolymer or glycerol microsphere
Glycerol
Colloidal Anhydrous Silica
Purified water
Sodium hydroxide to adjust the pH

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25 °C.

Do not freeze.

6.5 Nature and contents of container

White low density polyethylene tubes. Pack sizes: 15 g

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Galderma (UK) Limited,

Meridien House

69-71 Clarendon Road

Watford, Herts.

WD17 1DS, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 10590/0069

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

[To be completed on approval]

10 DATE OF REVISION OF THE TEXT

[To be completed on approval]

ACNECIDE® Face Wash 5% w/w Gel

Contains 5% Benzoyl Peroxide

Package leaflet: Information for the user
ACNECIDE FACE 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.

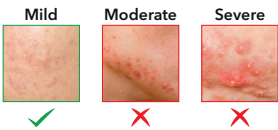
- Keep this leaflet. You may need to read it again.
- The product is for mild acne which is limited to the face only.
- **If your acne gets worse while using Acnecide Face Wash or if it does not improve within 12 weeks, it is important that you see your pharmacist or doctor for advice.**
- **Under treatment 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 Fash wash').
- 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.

What is in this leaflet

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

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

- Acnecide Face Wash contains the active ingredient benzoyl peroxide which kills the bacteria (germs) known as Propionibacterium acnes, one of the main causes of acne.
- Acnecide Face Wash 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:



- Acnecide Face 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 Face Wash

Do not use Acnecide Face 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.
- have any inflamed spots or larger lumps on your face, because you may have more severe acne and you should see your 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 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 doctor or pharmacist before using Acnecide Face Wash 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 doctor or pharmacist for advice.
- Avoid contact of the face wash 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 Face Wash should not be applied to damaged skin.
- Acnecide Fash Wash can cause increased sensitivity to sunlight, therefore excessive exposure to sunlight should be avoided. Sunbeds should not be used whilst using Acnecide Fash Wash.
- Avoid contact of the face wash with any coloured material including hair and dyed fabrics as it may result in bleaching or discolouration.
- Acnecide Face Wash may cause swelling and blistering of the skin. If these symptoms occur, use of the product should be discontinued.

Children and adolescents aged less than 12 years

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

Other medicines and Acnecide Face Wash

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 Face Wash.
- Do not use Acnecide Face Wash 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 doctor or pharmacist 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 doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Acnecide Face Wash has no or negligible effect on your ability to drive or use machines.

3. How to use Acnecide Face Wash

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

- Acnecide Face Wash is for EXTERNAL USE ONLY.

Adults and adolescents aged 12 years and over

- **Unless your doctor or pharmacist has told you otherwise:**
 - Acnecide Face Wash should be used once or twice daily to cover the affected skin areas of the face: Avoid contact with sensitive areas such as the eyes, mouth, nose lining and neck.
 - When you first start treatment, use Acnecide Face Wash 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 Wash does not affect your skin, or you have only mild burning and slight reddening and peeling after 2-3 days of use, you can use the wash 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 Wash 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 Wash 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.
- Wet the area to be treated
- Wash hands before use and place a small amount of Acnecide Face Wash on to the hands to wash the affected area.
- Contact time with the skin should be 1 to 2 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, neck or other very sensitive areas of the body. If the preparation enters the eye, wash thoroughly with water. In the event that Acnecide Face Wash is accidentally swallowed, contact your doctor.
- How long you will have to use Acnecide Face Wash will depend on how quickly your condition improves.
- **If your acne gets worse while using Acnecide Face Wash 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 doctor for advice. You may require additional or alternative treatment for your acne.**
- Acnecide Face Wash should not be used in adolescents and children under 12 years of age.

If you use more Acnecide Face Wash than you should

- If you use too much Acnecide Face 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 rare event that you accidentally swallow any of this product, seek medical advice.

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.

STOP using Acnecide Face Wash 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 Wash 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.

If your skin becomes severely irritated, or severe redness, itching or peeling of the skin occurs, discontinue use immediately and consult 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 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 Face 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 or outer carton. 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 protect the environment.

6. Contents of the pack and other information

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

Acnecide Face Wash is a white to off-white gel which is available in a 50g tube.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Galderma (UK) Limited, Meriden House, 69-71 Clarendon Road, Watford, Herts, WD17 1DS, UK (PL 10590/0070)

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

This leaflet was last revised in 03/2019

7. General advice for people with acne

- Try not 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. When cleansing your skin 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.

TUBE PLASTIQUE Ø35x100
PLAN n° 2.GD.02.DRA.0009.R01

ACNECIDE® Face Wash 5% w/w Gel 5% Benzoyl Peroxide 50g Gel  For the treatment of mild acne of the face		
PLEASE READ THE ENCLOSED LEAFLET BEFORE USE. WARNING: AVOID CONTACT WITH THE EYES, EYELIDS, LIPS AND OTHER DELICATE AREAS OF SKIN. FOR USE ON THE FACE ONLY. May bleach hair and dyed fabrics. DO NOT STORE ABOVE 25°C. KEEP OUT OF THE SIGHT AND REACH OF CHILDREN. Directions: Apply once or twice daily to cover the affected skin areas. Wet the area to be treated, apply the preparation to the hands and wash the affected area with the gel. Contact time with the skin should be 1 to 2 minutes followed by thorough rinsing with water and drying. CONTAINS: Hydrous Benzoyl Peroxide equivalent to Benzoyl Peroxide 5% w/w. Other ingredients are: Acrylates copolymer, glycerol, carbomer 940, sodium C14-C16 olefin sulfonate, sodium hydroxide (for pH adjustment), purified water.	PL 10590/0070 Marketing Authorisation Holder: Galderma (UK) Limited Meridien House 69-71 Clarendon Road Watford, Herts. WD17 1DS, UK  GALDERMA	
PXXXXX-X Batch No. / Exp. ▶		



Ligne de coupe

ACNECIDE®
5% Benzoyl Peroxide

For the treatment of mild
acne of the face

50g Gel

Face Wash

How Acnecide Face Wash 5% Gel works on acne spots: ?

Acnecide Face Wash 5% 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 Wash 5% Gel is suitable if: ✓

- You are over the age of 12 years.
- You have mild acne on the face.

Mild acne appears as predominately blackheads and whiteheads and there are few or no spots and pimples and no inflamed spots.



Do not use Acnecide Face Wash 5% Gel if you: ✕

- Have moderate acne with some inflamed red spots or pimples to severe acne with large bumps, many inflamed spots or previous scarring from acne of the face.
- Have acne on other parts of the body such as shoulders, back or chest.
- Have an allergy to any of the ingredients displayed on this pack.

How to use Acnecide Face Wash 5% Gel? 🌞🌙

Adults and adolescents aged 12 years and over.
Apply once or twice daily to cover the affected skin areas. Wet the area to be treated, apply the preparation to the hands and wash the affected area with the gel. Contact time with the skin should be 1 to 2 minutes followed by thorough rinsing with water and drying.

Please read the enclosed leaflet before use

- Do not use with other acne treatments and benzoyl peroxide products unless advised by your doctor.
- If your acne gets worse while using Acnecide Face Wash 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 you are pregnant or breastfeeding, consult your doctor or pharmacist before using any medicines.
- May bleach hair and dyed fabrics.

FOR USE ON THE FACE ONLY

BARCODE

CONTAINS:

Hydrous benzoyl peroxide equivalent to benzoyl peroxide 5% w/w. Other ingredients are: Acrylates copolymer, glycerol, carbomer 940, sodium C14-C16 olefin sulfonate, sodium hydroxide (for pH adjustment), purified water.

Galderma (UK) Limited

Meridien House, 69-71 Clarendon Road,
Watford, Herts. WD17 1DS, UK

PL 10590/0070

 GALDERMA

WARNING: AVOID CONTACT WITH THE EYES,
EYELIDS, LIPS AND OTHER DELICATE AREAS OF SKIN.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
DO NOT STORE ABOVE 25°C.

ACNECIDE®
5% Benzoyl Peroxide

Face Wash
5% w/w Gel

FIGHTS
THE
BACTERIA
THAT CAUSE
SPOTS

For the treatment of
mild acne of the face

50g Gel

Face Wash

ACNECIDE®
5% Benzoyl Peroxide

Face Wash
5% w/w Gel

FIGHTS
THE
BACTERIA
THAT CAUSE
SPOTS

For the treatment of
mild acne of the face

50g Gel

Face Wash

Batch Number:
Use Before:

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Acnecide Face Wash 5% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrous benzoyl peroxide equivalent to benzoyl peroxide 5% w/w

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel

White to off-white smooth gel

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Acnecide Face Wash is intended for the topical treatment of mild acne affecting the face, where comedones (blackheads and whiteheads) predominate, and there are few or no papules and pustules (acne spots and pimples) and no inflamed spots.

Acnecide Face Wash is indicated in adults and adolescents aged 12 years and over.

4.2 Posology and method of administration

Posology:

Adults and adolescents aged 12 years and over:

When first used Acnecide Face Wash should be applied once daily to cover the acne-affected skin areas before going to bed. After 2-3 days, if the treatment is well tolerated, the frequency of application can be increased to twice daily, in the morning and evening. The extent of any drying or peeling may be adjusted by modifying the dosage schedule (see section 4.4).

Paediatric population:

The safety and efficacy of Acnecide Face Wash in children aged less than 12 years have not been established. No data are available.

Method of administration:

For topical administration only

Wet the area to be treated, apply the preparation to the hands and wash the affected area with the gel. Contact time with the skin should be 1 to 2 minutes followed by thorough rinsing with water and drying.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

For external use only.

This product is not suitable for individuals with severe acne (characterised by large numbers of inflamed spots on the face or the presence of nodules and cysts), moderate acne (characterised by papules and pustules) or previous scarring from acne, who should seek treatment advice from a doctor.

Individuals with extensive acne lesions affecting other areas (e.g. the chest shoulders and back), which they want to treat, should consult their pharmacist or doctor. These lesions are often more difficult to treat and topical treatments may not be appropriate if they are widespread.

Individuals with mild acne that are particularly concerned by their condition should consult their doctor.

Acnecide Face Wash may cause swelling and blistering of the skin, if any of these symptoms occur, medication has to be discontinued.

In normal use, a mild burning sensation will probably be felt on first application and a moderate reddening and peeling of the skin will occur within a few days. During the first weeks of treatment a sudden increase in peeling will occur in most people, this is not harmful and will normally subside within a day or two if treatment is temporarily discontinued. Adjunctive use of moisturizers can help to limit the potential for skin irritation.

If severe irritation occurs, individuals should temporarily discontinue use until the irritation subsides. If treatment is restarted, the product should be applied less frequently (i.e. once a day instead of twice daily or alternate days instead of once a day). If severe irritation occurs again after treatment is restarted, discontinue use altogether.

Excessive application will not improve efficacy, but may increase the risk of skin irritation.

In the event of scarring following initial treatment with Acnecide Face Wash, treatment should be discontinued and advice should be sought from a doctor.

Acnecide Face Wash should not come into contact with the eyes, mouth, angles of the nose or mucous membranes. If the preparation enters the eye, wash thoroughly with water. Acnecide Face Wash should not be applied to the neck and other sensitive areas (around the eyes and mouth, angles of the nose or mucous membranes). Due to the risk of sensitisation, Acnecide Face Wash should not be applied to damaged skin.

As Acnecide Face Wash may cause increased sensitivity to sunlight, sunlamps should not be used and deliberate or prolonged exposure to sunlight or UV radiation should be avoided. When strong sunlight cannot be avoided, individuals should use a sunscreen product and wear protective clothing.

Contact with any coloured material including hair and dyed fabrics may result in bleaching or discoloration.

Acnecide Face Wash should not be used in conjunction with other benzoyl peroxide preparations (including other Acnecide products), nor with any other topical or systemic treatment(s) for acne except under medical supervision.

Individuals should cease use and seek medical advice if their condition deteriorates despite therapy or in cases of a lack of response after use for 12 weeks.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed. However, drugs with desquamative, irritant and drying effects should not be used concurrently with Acnecide Face Wash.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is no safety concern relating to the effects of cutaneously applied benzoyl peroxide on reproductive function, fertility, teratogenicity, embryotoxicity, or peri- and post- natal development from animal data. In widespread clinical use for the cutaneous treatment of acne vulgaris, at concentrations up to 10% w/w for several decades, benzoyl peroxide has never been associated with such effects. Acnecide Face Wash should only be used by a pregnant woman under medical supervision.

Breast-feeding

It is unknown whether benzoyl peroxide/metabolites are excreted in human milk. A risk to the new-borns/infants cannot be excluded and the preparation should not be applied on the chest in nursing women to avoid accidental transfer to the infant. Acnecide Face Wash should only be used by a nursing woman under medical supervision.

4.7 Effects on ability to drive and use machines

Acnecide Face Wash has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The adverse reactions resulting from clinical trials are all skin disorders. They are reversible when treatment is reduced in frequency or discontinued.

The following categories are used to indicate the frequency of occurrence of adverse effects:

Very common ($\geq 1/10$)

Common ($\geq 1/100$ to $< 1/10$)

Uncommon ($\geq 1/1,000$ to $< 1/100$)

Rare ($\geq 1/10,000$ to $< 1/1,000$)

Very rare ($< 1/10,000$)

Unknown (Frequency not assessable based on the available data).

They are presented in the table below:

Skin and subcutaneous tissue disorders	Very common ($\geq 1/10$)	Dry skin, Erythema, Skin exfoliation, (peeling), Skin burning sensation
	Common ($\geq 1/100$ to $< 1/10$)	Pruritus, Pain of skin (pain, stinging), Skin irritation, (irritant contact dermatitis)
	Uncommon ($\geq 1/1,000$ to $< 1/100$)	Allergic contact dermatitis

Swelling face and allergic reactions, including application site hypersensitivity and anaphylaxis (not know frequency) have been reported during post-marketing surveillance.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Acnecide Face Wash is for topical use only. If the medication is applied excessively, no more rapid or better results will be obtained and severe irritation might develop. In this event, treatment must be discontinued and appropriate symptomatic therapy, including the use of moisturizers, should be instituted.

In the case of accidental ingestion, urgent medical attention is required. Expert advice should be sought and supportive measures instituted.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-acne preparations for topical use, ATC Code: D10AE01

Benzoyl peroxide has been shown to exert antibacterial activity against *Propionibacterium acnes*, the organism implicated in acne vulgaris. Additionally benzoyl peroxide has demonstrated exfoliative and comedolytic activities both of which are beneficial in the treatment of acne.

5.2 Pharmacokinetic properties

The percutaneous penetration of benzoyl peroxide in rat, rabbit, monkey and man is low. The majority of the penetrated benzoyl peroxide is converted into benzoic acid which after absorption into the systemic circulation is rapidly eliminated by the kidney. There is no evidence for any tissue accumulation.

5.3 Preclinical safety data

In animal studies by the cutaneous route, benzoyl peroxide is associated with a minimal to moderate skin irritation potential including erythema and oedema. Phototoxic and photoallergic reactions have been reported for benzoyl peroxide therapy.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acrylates copolymer

Glycerol

Carbomer 940

Sodium C14-C16 Olefin Sulfonate

Sodium Hydroxide (for pH adjustment)

Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

18 months

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and contents of container

White high density polyethylene tube, fitted with a white polypropylene screw cap.

Pack sizes: 50g

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Galderma (UK) Limited,

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Herts

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UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 10590/0070

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

[To be completed on approval]

10 DATE OF REVISION OF THE TEXT

[To be completed on approval]
