

IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0590/007/002

Case No: 2047174

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Galderma (UK) Ltd

Meridien House, 69-71 Clarendon Road, Watford, Herts WD17 1DS, United Kingdom

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Acnecide 10 %w/w Gel

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **11/03/2008**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Acnecide 10% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrous benzoyl peroxide equivalent to Benzoyl Peroxide 10 % w/w.

Excipient: Propylene glycol 40mg/g

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.

White, smooth gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Acnecide is indicated in the management of acne vulgaris.

4.2 Posology and method of administration

Topical administration only.

Adults and children:

After washing with a mild cleanser and water, apply once or twice daily or as directed to the affected areas. The degree of drying and peeling can be adjusted by modification of the dosage schedule. It is recommended to initiate the treatment with Acnecide Gel 5%. In case adequate results are not achieved with the 5% gel, treatment with the 10% gel may be started. Persons with sensitive skin should be directed to apply the gel once daily before going to bed.

4.3 Contraindications

Use in patients hypersensitive to benzoyl peroxide.

4.4 Special warnings and precautions for use

1. For external use only.
2. If no response occurs within four weeks the use of the product should be discontinued and a doctor consulted. In any event a single course of treatment should not extend beyond three months.
3. This product should be kept from contact with eyes, mouth, angles of the nose or mucous membranes. If accidental contact occurs, rinse with water.
4. Benzoyl peroxide should not be used during extensive exposure to sunlight or ultraviolet light.

5. Fair-skinned individuals are likely to be particularly susceptible to irritation.
6. If undue redness or discomfort occurs the product should not be used until the doctor has been consulted.
7. Acnecide may bleach hair and coloured fabrics.
8. Concurrent use with PABA-containing sunscreens may result in transient discoloration of the skin.
9. Due to the risk of sensitisation Acnecide gel should not be applied to damaged skin.
10. Caution should be exercised when applying Acnecide Gel to the neck and other sensitive areas.
11. During the first weeks of treatment, a sudden increase in peeling will occur in most patients, this is not harmful and will normally subside within a day or two if treatment is temporarily discontinued. If severe irritation occurs, patients should be directed to use the medication less frequently, to temporarily discontinue use or to discontinue use altogether.

4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions with other medications which might be used cutaneously and concurrently with Acnecide Gel. However, drugs with desquamative, irritant and drying effects should not be used concurrently with Acnecide Gel.

4.6 Pregnancy and lactation

There is a lack of therapeutic experience of benzoyl peroxide in pregnancy and lactation and as such it should not be used unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

Based on the pharmacodynamic profile and extensive clinical experience, performance related to driving and using machines should not be affected during treatment with Acnecide Gel.

4.8 Undesirable effects

Application of benzoyl peroxide may produce an initial stinging effect.

As with all keratolytic substances, itching, reddening, burning, peeling of skin and a feeling of skin tension may occur. This may be relieved by the use of a moisturising cream or by temporary interruption of use.

In rare cases, a contact dermatitis including face oedema may occur, in which event treatment should be stopped immediately.

4.9 Overdose

Overdosage may cause the skin to become excessively red and sore during the first few days of treatment. Acnecide Gel should be applied less often until this phase has passed. If excessive irritation develops, discontinue treatment and consult the physician.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Benzoyl peroxide is an established and effective keratolytic and comedolytic 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 pharmacokinetic characteristics for benzoyl peroxide have not been established and little is known about the percutaneous penetration, metabolism and excretion of benzoyl peroxide, although it is likely that benzoic acid is a major metabolite.

5.3 Preclinical safety data

There is no evidence of systemic toxicity caused by benzoyl peroxide in humans. 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
Propylene glycol
Acrylates copolymer
Glycerol
Colloidal anhydrous silica
Purified Water
Sodium hydroxide to adjust the pH

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 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 with white polypropylene screw caps containing 60 g gel.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

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

PA 590/7/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th April 1984

Date of last renewal: 31st October 2007

10 DATE OF REVISION OF THE TEXT

November 2007