Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Acnecide 5% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients with known effect:
One gram of gel contains 40 mg of propylene glycol (E1520).

For a 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 is indicated in the management of acne vulgaris.

4.2 Posology and method of administration

Topical administration only.

Adults and children:
Before each application, the skin should be cleaned and dried. Apply in a thin layer once or twice daily or as directed to the affected areas.
Persons with sensitive skin should be directed to apply the gel once daily before going to bed. The extent of any drying or peeling may be adjusted by modifying the dosage schedule.

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

1. For external use only.

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

3. 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.

4. This product should be kept from contact with eyes, mouth, angles of the nose or mucous membranes. If accidental contact occurs, rinse with water.

5. Repeated exposure to sunlight or UV radiation should be avoided.

6. Fair-skinned individuals are likely to be particularly susceptible to irritation.

7. If undue redness or discomfort occurs the product should not be used until the doctor has been consulted.

8. Acnecide may bleach hair and coloured fabrics.

9. Concurrent use with PABA-containing sunscreens may result in transient discoloration of the skin.

10. Due to the risk of sensitisation Acnecide gel should not be applied to damaged skin.

11. Caution should be exercised when applying Acnecide Gel to the neck and other sensitive areas.

12. 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.
13. This medicine contains 40 mg of propylene glycol (E1520) in each gram, which is equivalent to 4.0 % w/w. It may cause skin irritation.

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 Fertility, pregnancy and lactation

Pregnancy
There are limited data on the use of topical benzoyl peroxide in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3). No effects during pregnancy are anticipated since systemic exposure to benzoyl peroxide is very limited. However, benzoyl peroxide should be used during pregnancy only if the expected benefit justifies the potential risk to the foetus.

Breast-feeding
It is not known whether benzoyl peroxide/metabolites are excreted in human milk. A risk to the new-borns/infants cannot be excluded. Caution should be exercised when benzoyl peroxide is administered to a nursing woman and the preparation should not be applied on the chest to avoid accidental transfer to the infant.

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

The adverse reactions resulting from clinical trials are all skin disorders. They are reversible when treatment is reduced in frequency or discontinued or by the use of a moisturizing cream.
The following categories are used to indicate the frequency of occurrence of adverse effects:

Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥ 1/1,000 to <1/100)
Rare (≥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	Dry skin Erythema Skin exfoliation (peeling) Skin burning sensation
	Common	Pruritus Pain of skin (pain, stinging)

		Skin irritation (irritant contact dermatitis)
	Uncommon	Allergic contact dermatitis

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

In case of allergic contact dermatitis or swelling face, treatment should be stopped immediately.

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 HPRA Pharmacovigilance, Website: www.hpra.ie

4.9 Overdose

Benzoyl peroxide 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 should be instituted.

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 Cutibacterium 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

An oral administration, fertility and embryo-foetal development study in Sprague-Dawley rats observed effects on reproductive parameters at exposures considered sufficiently in excess of the maximum human exposure, indicating little relevance to clinical use. 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 (E1520)
Acrylates copolymer
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 with white polypropylene screw caps. Pack sizes 30g and 60g.
Not all pack sizes may be marketed.

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 International S.A.S.
La Défense 4 Tour Europlaza
20 Avenue André Prothin
Paris La Défense Cedex
92927
France

8 MARKETING AUTHORISATION NUMBER

PA22743/001/001

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

August 2022