Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Acnecide Wash 5 % w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.

White to off white gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Acnecide Wash is intended for the cutaneous treatment of acne vulgaris of the face, chest and back, where comedones, papules predominate.

4.2 Posology and method of administration

For cutaneous (topical) administration only.

Unless otherwise directed, Acnecide Wash should be applied 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 5 minutes followed by thorough rinsing with water and drying.

4.3 Contraindications

Hypersensitivity to the ingredients of the preparation.

4.4 Special warnings and precautions for use

For external use only.

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 patients, this is not harmful and will normally subside within a day or two if treatment is temporarily discontinued.
Acnecide may cause swelling and blistering of the skin, if any of these symptoms occur, medication has to be discontinued.
If severe irritation occurs, patients should be directed to use the medication less frequently, to temporarily discontinue use or to discontinue use altogether.

Acnecide 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. Caution should be exercised when applying Acnecide Wash to the neck and other sensitive areas. Due to the risk of sensitisation, Acnecide Wash should not be applied to damaged skin.

The repeated exposure to sunlight or UV irradiation should be avoided.

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

4.5 Interaction with other medicinal products and other forms of interactions

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

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 peroxideis 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 Wash.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Acnecide Wash is for cutaneous 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 should be instituted.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Benzoyl peroxide has been shown to have potent broad spectrum antimicrobial activity, particularly against Propionibacterium acnes which is abnormally present in acne affected hair follicles. 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. There is no evidence that cutaneous application of the proposed clinical doses of Acnecide Wash should be associated with any systemic adverse reactions in humans.

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

Acrylates copolymer
Glycerol
Carbomer 940 (Carbopol 980)
Sodium C_{14}-C_{16} Olefin Sulfonate
Sodium Hydroxide
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, 100 g.

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

Squeeze the tube or bottle gently to place on the hands a quantity of gel sufficient to wash the area to be treated. Wash hands thoroughly and replace the cap tightly after use.

7 MARKETING AUTHORISATION HOLDER

Galderma International, Tour Europlaza,20, Avenue André Prothin,La Défense 4,92927 Paris,La Défense,CEDEX,France

8 MARKETING AUTHORISATION NUMBER

PA22743/001/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st October 1997
Date of last renewal: 31st October 2007

10 DATE OF REVISION OF THE TEXT

May 2022