

**IRISH MEDICINES BOARD ACTS 1995 AND 2006**

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

**(S.I. No.540 of 2007)**

**PA0590/007/004**

Case No: 2036964

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 Wash 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 **31/10/2007**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Acnecide Wash 10 % w/w Gel

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrous Benzoyl Peroxide equivalent to Benzoyl peroxide 10 % 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 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

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.

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.

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 interaction**

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 Pregnancy and lactation**

There are no published reports relating to the effects of benzoyl peroxide on reproduction function, fertility, teratogenicity, embryotoxicity, or peri- and post-natal development in animals. 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 effects on these parameters in humans. Although safe for use during pregnancy, Acnecide Wash should only be used by a pregnant woman if clearly needed.

It is not known whether benzoyl peroxide is excreted in animal or human milk. Because many drugs are excreted in human milk, caution should be exercised when Acnecide is administered to a nursing woman. In this event, 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**

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

#### **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

In animal studies by the cutaneous route, benzoyl peroxide is associated with a minimal to moderate skin irritation potential including erythema and oedema.

The low systemic exposure to benzoyl peroxide and to its major degradation product, benzoic acid, assures that no acute or chronic systemic toxicity occur. Phototoxic and photoallergic reactions have been reported for benzoyl peroxide therapy, although the relevant scientific literature is contradictory.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Acrylates copolymer  
Glycerol  
Carbomer 940 (Carbopol 980)  
Sodium C<sub>14</sub>-C<sub>16</sub> Olefin Sulfonate  
Sodium Hydroxide  
Purified Water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf Life

2 years.

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

Pack sizes: tube 100g, bottle 200ml.

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 (UK) Limited  
Meridien House  
69-71 Clarendon Road  
Watford  
Herts  
WD17 1DS  
UK

**8 MARKETING AUTHORISATION NUMBER**

PA 590/7/4

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

Date of first authorisation: 31<sup>st</sup> October 1997

Date of last renewal: 31<sup>st</sup> October 2007

**10 DATE OF REVISION OF THE TEXT**

November 2007