

## **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 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 Wash is intended for the cutaneous treatment of acne vulgaris of the face, chest and back, where comedones and 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 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.

Acnecide 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 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.

Patients should be advised that excessive application will not improve efficacy, but may increase the risk of skin irritation.

Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy may occur, which sometimes may be severe, especially with the use of peeling, desquamating, or abrasive agents.

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.

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

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

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

Patients should be advised to cease use and seek medical advice if their condition deteriorates despite therapy, or in cases of a persistent lack of response.

Acnecide Wash is intended FOR EXTERNAL USE ONLY.

#### **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 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. 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 Wash should be used by a pregnant woman only if clearly needed.

#### Breast-feeding

It is unknown 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

Acnecide 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 ( $\geq 1/1000$ 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](http://www.mhra.gov.uk/yellowcard).

#### 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.

In the case of accidental ingestion, urgent medical attention is required. Expect 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 C<sub>14</sub>-C<sub>16</sub> Olefin Sulfonate

Sodium Hydroxide (for pH adjustment)

Purified Water

## **6.2 Incompatibilities**

Not applicable

## **6.3 Shelf life**

18 months

After first opening: 6 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, 100g.

Not all pack sizes may be marketed.

## **6.6 Special precautions for disposal**

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 (U.K.) Limited,  
Evergreen House North,  
Grafton Place,  
London,  
England,  
NW1 2DX

## **8 MARKETING AUTHORISATION NUMBER(S)**

PL 10590/0026

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

15/04/2002 / 05/03/2009

**10 DATE OF REVISION OF THE TEXT**

27/02/2026