

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Acnegel 5% w/w

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Gel

A white creamy homogeneous gel.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

Acnegel is indicated for the treatment of mild to moderate acne vulgaris.

##### 4.2 Posology and method of administration

###### Adults

Apply to the whole of the affected area once or twice daily. Wash with soap and water prior to application.

###### Paediatric use

The safety and efficacy of Acnegel has not been established in children since acne vulgaris rarely presents in this age group.

###### Elderly patients

There are no specific recommendations. Acne vulgaris does not present in the elderly.

##### 4.3 Contraindications

Patients with known hypersensitivity to any of the ingredients should not use the product.

##### 4.4 Special warnings and special precautions for use

Avoid contact with the eyes, mouth and other mucous membranes. Care should be taken when applying the product to the neck and other sensitive areas.

The product may bleach coloured or dyed fabrics.

The product should only be used with caution in areas of thin or sensitive skin. Fair skinned individuals are likely to be particularly sensitive to irritation.

Benzoyl peroxide should not be used in patients with fair or sensitive skin if there is concurrent extensive exposure to sunlight or ultraviolet light.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

None known.

#### **4.6 Pregnancy and lactation**

There are no restrictions on the use of Acnegel during pregnancy and lactation.

#### **4.7 Effects on ability to drive and use machines**

None.

#### **4.8 Undesirable effects**

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 few weeks of treatment, a sudden increase in peeling will occur in most patients; this is not harmful and will normally subside in a day or two if treatment is temporarily discontinued.

#### **4.9 Overdose**

Not applicable.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Benzoyl peroxide has antibacterial activity against *Propionibacterium acnes*, the organism implicated in acne vulgaris. It has keratolytic activity and is sebostatic, counteracting the hyperkeratinisation and excessive sebum production associated with acne.

#### **5.2 Pharmacokinetic properties**

After topical application, benzoyl peroxide is absorbed in varying quantities through the skin of man and animals.

Radio-labelled studies have shown that absorption of benzoyl peroxide through the skin can only occur following its conversion to benzoic acid. Benzoic acid is mostly conjugated to form hippuric acid which is excreted via the kidneys.

#### **5.3 Preclinical safety data**

Animal toxicity studies of benzoyl peroxide have shown that the compound is non-toxic when applied topically

Benzoic acid, to which benzoyl peroxide is converted prior to absorption, has a wide margin of safety. Benzoic acid is an approved food additive.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Colloidal Magnesium Aluminium Silicate  
Hypromellose  
Macrogol Lauril Ether  
Denatured Ethanol  
Citric Acid  
Alpine Essence 6565A  
Purified Water

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf Life**

3 years.

### **6.4 Special precautions for storage**

Do not store above 25°C.

### **6.5 Nature and contents of container**

Lacquered aluminium tubes with white polypropylene screw caps containing 50 g.

### **6.6 Instructions for use and handling**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Stiefel Laboratories (UK) Ltd,  
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## **8 MARKETING AUTHORISATION NUMBER**

PA 144/28/1

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

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Date of last renewal: 25<sup>th</sup> May 2004

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