

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

PanOxyl Aquacream 2.5% w/w

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzoyl peroxide 2.5% w/w (as hydrous benzoyl peroxide).

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Cream.  
Smooth white cream free from gritty particles.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

PanOxyl Aquacream is indicated for the treatment of Acne Vulgaris.

##### 4.2 Posology and method of administration

*Adults and children over 6 years of age (including the elderly):*

Wash the face, rinse and then dry with a soft, clean towel. Using a fingertip, apply the cream once a day to the spots. Massage gently until the cream has vanished. Wash hands after use.

With very fair or sensitive skin apply cautiously for the first few days to avoid redness and peeling.

Not recommended for use on children under 6 years of age.

##### 4.3 Contraindications

Hypersensitivity to benzoyl peroxide or any of the other ingredients.

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

Avoid contact with the eyes, lips and mouth.

People with a known intolerance to benzoyl peroxide should not use PanOxyl Aquacream; if unsure or the product has not been used before, rub in PanOxyl Aquacream to a small area of the lower arm above the wrist at least 48 hours before use. If swelling or itching occurs with severe redness do not use PanOxyl Aquacream.

Mild burning or tingling may be felt when PanOxyl Aquacream is applied. Mild to moderate redness and peeling sometimes arise with continued use. This indicates that PanOxyl Aquacream is working. If the reaction is excessive, decrease the quantity and frequency of application and if it persists, seek medical advice.

Do not use PanOxyl Aquacream continuously for more than one month without medical advice.

If PanOxyl Aquacream comes into contact with fabric, wash immediately in cold water as it causes bleaching of coloured fabrics.

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

None known.

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

Use during pregnancy and lactation is not contraindicated. However, as with all medicines in pregnancy caution should be exercised.

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

None known.

#### **4.8 Undesirable effects**

Redness and peeling may occur. Excessive irritation or an allergic reaction may occasionally occur in some individuals.

#### **4.9 Overdose**

Over-use is likely to cause excessive localised redness and peeling due to the drying action of benzoyl peroxide. Medical advice should be sought if this does not subside on withdrawal of the product.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Benzoyl peroxide has keratolytic activity coupled with antibacterial activity against *Propionibacterium acnes*, the organism implicated in acne vulgaris.

#### **5.2 Pharmacokinetic properties**

Benzoyl peroxide absorbed through the skin is mostly metabolised to benzoic acid which is then rapidly excreted in the urine.

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

There are no preclinical data of any relevance additional to that already included in other sections of the SmPC.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Isopropyl palmitate  
Macrogol (1000) monostearate  
Glyceryl monostearate  
Propylene glycol  
Stearic acid  
Zinc stearate  
Purified water

## **6.2 Incompatibilities**

Not applicable

## **6.3 Shelf Life**

Three years.

## **6.4 Special precautions for storage**

Store below 25°C.

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

20 g aluminium tube with internal phenolic resin lacquer.

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

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Stiefel Laboratories (UK) Ltd  
Holtspur Lane  
Wooburn Green  
High Wycombe  
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## **8 MARKETING AUTHORISATION NUMBER**

PA 144/11/11

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

Date of first authorisation: 10<sup>th</sup> December 1998

Date of last renewal: 10<sup>th</sup> December 2003

## **10 DATE OF REVISION OF THE TEXT**

August 2004