

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

PanOxyl 5% Cream

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzoyl Peroxide Hydrrous Ph. Eur. equivalent to Benzoyl Peroxide anhydrous 5.00 % w/w.

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Cream

A smooth homogeneous white cream.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

PanOxyl 5 Cream is indicated for the treatment of acne vulgaris.

##### 4.2 Posology and method of administration

Apply to the affected area once daily. Washing with soap and water prior to application greatly enhances the efficacy of the preparation.

##### 4.3 Contraindications

Patients with a known hypersensitivity to benzoyl peroxide should not use this product.

##### 4.4 Special warnings and 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 dyed fabrics.

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

None.

##### 4.6 Pregnancy and lactation

There are no restrictions on the use of the product during pregnancy or 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 a sebostatic and keratolytic activity counteracting the hyperkeratinisation and excessive sebum secretion associated with acne vulgaris. It has antibacterial activity against *Propionibacterium acnes*, the organism implicated in acne vulgaris. The use of benzoyl peroxide in the treatment of acne is well established.

## 5.2 Pharmacokinetic properties

Published pharmacokinetic studies have demonstrated that benzoyl peroxide penetrates the skin following topical application, undergoing rapid metabolism to benzoic acid, which is quickly eliminated, without accumulation. A lack of systemic effects following topical administration of benzoyl peroxide has been clearly shown.

## 5.3 Preclinical safety data

Not applicable. Benzoyl peroxide has been in wide-spread use for many years. The relevant information is given in section 4 of the Summary of Product Characteristics.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Isopropyl palmitate  
Macrogol 1000 monostearate  
Glycerol monostearate  
Propylene glycol  
Stearic acid  
Zinc stearate  
Purified water

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf Life

3 years.

## 6.4 Special precautions for storage

Store below 25°C.

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

Internally lacquered aluminium tubes of 40g.

## **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**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

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## **8 MARKETING AUTHORISATION NUMBER**

PA 144/11/8

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

Date of first authorisation: 01 October 1984

Date of last renewal: 01 October 2004

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

August 2006