

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Benzoyl Peroxide Cream 10 %

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzoyl Peroxide 10 % w/w.

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Cream  
Creamy, white thixotropic cream.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

Acne Vulgaris.

##### 4.2 Posology and method of administration

For topical use only.

Adults, children and the elderly:  
By gentle massage over all the affected area two or three times daily.

##### 4.3 Contraindications

Acne Rosacea. Patients with known sensitivity to Benzoyl Peroxide.

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

Contact with mouth and eyes should be avoided. Care should be taken to avoid contact with dyed fabrics as this product may adversely affect dye-fastness.

Individuals may notice dry skin.

In a few isolated cases, overreaction to Benzoyl Peroxide Cream 10% may occur. To minimise this possibility, select a small area of skin behind the ear, apply the cream and leave for twelve hours. If severe irritation or redness occurs, do not proceed with the treatment.

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

Benzoyl Peroxide is an oxidising agent. Hence, Benzoyl Peroxide Cream 10% should not be used at the same time as other topical agents which would react with an oxidising agent.

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

Benzoyl Peroxide Cream 10% is not contra-indicated in pregnancy or lactation.

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

None known.

#### **4.8 Undesirable effects**

If symptoms persist or if the condition worsens or if irritation, itch or rash occurs, treatment should be discontinued and the physician or pharmacist consulted for advice.

#### **4.9 Overdose**

If accidentally ingested symptomatic and supportive management is advised.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Benzoyl Peroxide is a mild keratolytic agent and also has antiseptic properties. It has a local effect only and is not absorbed by the skin.

#### **5.2 Pharmacokinetic properties**

Not applicable.

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

Not applicable.

### **6 PHARMACEUTICAL PARTICULARS**

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

White soft paraffin  
Emulgade F (consisting of Cetostearyl alcohol, Sodium cetostearyl sulphate and PEG – 40 Castor oil)  
Edetic acid  
Sodium dihydrogen phosphate dihydrate  
Lactic acid  
Maize starch  
Purified water

#### **6.2 Incompatibilities**

Any topical agent that would react with an oxidising agent.

#### **6.3 Shelf Life**

3 years.

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

Do not store above 25°C.  
Keep the container tightly closed.

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

Heat-sealed, low-density polyethylene tubes with a flush-fitting polypropylene cap containing 50g of product. Each tube is cartoned and contains a package insert.

#### **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**

Gently massage over all the affected area two or three times daily.

### **7 MARKETING AUTHORISATION HOLDER**

Ferndale Pharmaceuticals Ltd  
12 York Place  
Leeds LS1 2DS  
United Kingdom

### **8 MARKETING AUTHORISATION NUMBER**

PA 1155/7/2

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

Date of first authorisation: 6 November 1987

Date of last renewal: 6 November 2002

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

June 2005