

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Hioxyl Cream

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrogen Peroxide 1.50 % w/w.

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Cream

Smooth, white, non-greasy cream with virtually no odour.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

Hioxyl Cream is indicated in the treatment of leg ulcers, pressure sores, minor wounds and infections of the skin.

##### 4.2 Posology and method of administration

Route of administration.

For topical use only.

##### Adults, Children and the Elderly

Hioxyl Cream is applied freely using a piece of lint or gauze. If necessary it may be covered with a dressing. The application is repeated as required.

##### 4.3 Contraindications

There are no known contra-indications except true hypersensitivity to the active ingredient.

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

Care should be taken to avoid usage with other medicaments due to possible interaction negating the active ingredient. Care should be taken to avoid contact with dyed fabrics as this product may adversely affect dye fastness.

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

Hydrogen Peroxide is an oxidising agent and should not be used in conjunction with other topical agents which would react with an oxidising agent.

##### 4.6 Pregnancy and lactation

Hioxyl Cream is not contra-indicated in pregnancy or lactation.

## 4.7 Effects on ability to drive and use machines

Not applicable. Hioxyl Cream is for topical use only.

## 4.8 Undesirable effects

Not applicable.

## 4.9 Overdose

Not applicable. Hioxyl Cream is for topical use only.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

The antiseptic effect of hydrogen peroxide is a result of its ready release of oxygen when applied to tissues. The effect only lasts as long as oxygen is being released, and for solutions of hydrogen peroxide, this is of only short duration.

Hioxyl Cream is a unique formulation in which hydrogen peroxide has been stabilised in a soothing, easy to apply cream to give prolonged antiseptic action.

## 5.2 Pharmacokinetic properties

Not applicable.

## 5.3 Preclinical safety data

None stated.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Lactic acid  
White soft paraffin  
Sodium acid phosphate  
Maize starch  
Cetylstearyl alcohol  
Sodium cetylstearyl sulphate  
Polyethylene glycol 40-castor oil  
Purified water

## 6.2 Incompatibilities

Hioxyl cream should not be used at the same time as other topical medicaments. It is an oxidising agent and other topical agents may negate the effect for the active ingredient.

## 6.3 Shelf Life

18 months.

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

Do not store above 25°C.

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

Low density polyethylene tubes 25 g and 100 g with flush fitting cap.

#### **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**

Ferndale Pharmaceuticals Ltd  
12 York Place  
Leeds LS1 2DS  
UK

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

Date of first authorisation: 30 August 1983

Date of last renewal: 30 August 2003

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

May 2005