

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Hemocane Cream

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lignocaine Hydrochloride Ph. Eur	0.65	% w/w
Zinc Oxide Ph. Eur	10.00	% w/w
Bismuth Oxide	2.00	% w/w
Cinnamic Acid B.P	0.45	% w/w
Benzoic Acid Ph. Eur	0.40	% w/w

#### 3 PHARMACEUTICAL FORM

A smooth white odourless cream intended for external use.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

Treatment of the symptoms of haemorrhoids and allied ano-rectal conditions.

##### 4.2 Posology and method of administration

Adults - apply morning and night and after bowel movements until the condition is controlled. Not recommended for children.

##### 4.3 Contraindications

Hypersensitivity to any of the ingredients.

Untreated infectious conditions, of bacterial, viral, tuberculous or fungal origin.

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

If symptoms persist or worsen, or if an allergic reaction occurs, discontinue use immediately and consult your doctor. Persons who suffer from haemorrhoids are advised to consult their doctor.

Keep out of reach of children.

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

None.

##### 4.6 Pregnancy and lactation

Not to be used in pregnancy unless considered essential by the physician.

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

None.

#### **4.8 Undesirable effects**

None.

#### **4.9 Overdose**

Overdose is unlikely to occur with the cream. Symptoms would be associated with high plasma levels of lignocaine hydrochloride.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Lignocaine has local anaesthetic properties. Zinc oxide and bismuth oxide, when applied locally, have mild astringent actions and provide a soothing, protective action on mucous membranes and raw surfaces. Benzoic and cinnamic acid have mild ant-septic properties.

#### **5.2 Pharmacokinetic properties**

Lignocaine is readily absorbed from the mucous membranes and through damaged skin. Intravenous data shows plasma concentrations to decline rapidly with a half life of about 10 minutes. The elimination half life is about 2 hours and excretion is through the kidneys. These effects are considered to have a minimal effect from the application of HEMOCANE Cream.

Zinc oxide and bismuth oxide are insoluble in water and are not absorbed in any appreciable amount.

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

None stated.

### **6 PHARMACEUTICAL PARTICULARS**

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

Propylene glycol  
Glycerol  
Cetostearyl alcohol  
Polawax EM 3354  
Arlacel 83  
Polysorbate 80

#### **6.2 Incompatibilities**

None.

#### **6.3 Shelf Life**

3 years.

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

Store below 25°C.

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

25 and 45 g internally lacquered aluminium tubes in a cardboard carton together with a pile pipe.

#### **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**

None stated.

### **7 MARKETING AUTHORISATION HOLDER**

Eastern Pharmaceuticals Limited  
Coomb House  
7 St. John's Road  
Isleworth  
Middlesex TW7 6NA  
United Kingdom

### **8 MARKETING AUTHORISATION NUMBER**

PA 0739/002/001

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

Date of first authorisation: 16 March 1990

Date of last renewal: 16 March 2000

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

November 2000