

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Ichthammol Glycerin BPC

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Ichthammol BPC 1973 10.0% w/w

For excipients, see section 6.1.

### **3 PHARMACEUTICAL FORM**

Topical bacteriostatic moisturiser  
Viscous black liquid

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

For the treatment of chronic eczema.

#### **4.2. Posology and Method of Administration**

Adults, the elderly and children under 12 years

To be applied topically 1-3 times daily.

Route of administration

Topical.

#### **4.3 Contraindications**

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

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

Do not apply to broken skin. For external use only. Keep out of the reach of children. Store at a temperature not exceeding 25° C in well closed containers.

#### **4.5 Interactions with other Medicaments and other forms of Interaction**

No significant interactions have been reported.

#### **4.6 Fertility, pregnancy and lactation**

No significant problems have been reported either with pregnant women or with nursing mothers who are breast feeding; however, as with many other medicines, its use especially in the first 3 months of pregnancy, is recommended only when the benefits outweigh any risks.

#### **4.7 Effects on Ability to Drive and Use Machines**

None known.

#### **4.8 Undesirable effects**

Skin irritation has been reported.

##### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

#### **4.9 Overdose**

Overdosage is unlikely to present a significant risk as it is applied topically; however, should it occur then treatment includes induction of emesis followed by supportive therapy which may include gastric lavage.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1. Pharmacodynamic Properties**

Ichthammol has a slight bacteriostatic effect and acts in a similar manner to Coal Tar BP being used in the treatment of the less acute forms of eczema.

Glycerin is a humectant with emollient properties.

### **5.2. Pharmacokinetic Properties**

Ichthammol is applied externally. There is little information available regarding its pharmacokinetics although it is probably not absorbed through intact skin.

### **5.3. Preclinical Safety Data**

No relevant data.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1. List of Excipients**

Glycerol.

### **6.2. Incompatibilities**

No significant major incompatibilities have been reported

### **6.3 Shelf life**

5 years

### **6.4. Special Precautions for Storage**

Store below 25°C.

#### **6.5. Nature and Contents of Container**

##### Dispensing pack

2 litre HDPE bottle, plastic screw cap with an aluminium foil lined EPE liner.

500 ml HDPE bottle with a wadless polypropylene screw cap.

##### Patient packs or OTC packs as appropriate

500 ml HDPE bottle with a wadless polypropylene screw cap.

200 ml amber glass bottle with a white Jay cap closure.

#### **6.6 Special precautions for disposal**

None stated

#### **7. MARKETING AUTHORISATION HOLDER**

Wise Pharmaceuticals Limited,  
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#### **8. MARKETING AUTHORISATION NUMBER**

PL 18374/0020

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

17<sup>th</sup> February 2005

**10 DATE OF REVISION OF THE TEXT**

25/01/2016