

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Hirudoid Gel

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

Heparinoid 0.3% w/w (Equivalent to 25,000 Units per 100g gel).

### **3. PHARMACEUTICAL FORM**

Topical gel.

### **4. CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

Hirudoid is indicated for the treatment of superficial thrombophlebitis and the soothing relief of superficial bruising and haematoma.

#### **4.2 Posology and method of administration**

Adults, the elderly and children over 5 years of age:

Two to six inches (5-15 cm) to be applied, as a thin layer, up to four times a day to the affected area. Recommended when its cooling effect and rapid action are required.

#### **4.3 Contraindications**

Not to be used on large areas of skin, broken skin, sensitive areas of skin or mucous membranes. Not to be used in individuals with a known sensitivity to any active or inactive component of the formulation. Not to be used in children under 5 years of age.

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

For external use only. If symptoms persist or worsen, seek medical advice. Do not exceed the stated dose.

#### **4.5 Interactions with other medicinal products and other forms of interaction**

None known.

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

There is no evidence to suggest that Hirudoid should not be used during pregnancy and lactation.

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

None.

#### **4.8 Undesirable effects**

None known.

#### **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 ADR reporting website at: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal).

#### **4.9 Overdose**

In the absence of any reports of the accidental ingestion of Hirudoid, no specific advice is available. General supportive measures may be appropriate.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Heparinoid is recognised as having: a weak inhibitory effect on PGE<sub>2</sub> synthesis and an indirect effect on LTB<sub>4</sub> production (based on in vitro studies), anti-coagulant activity (as a heparinoid), thrombolytic activity (through potentiation of urokinase activity), anti-exudatory activity (through inhibition of hyaluronidase).

#### **5.2 Pharmacokinetic properties**

Radiochemical studies of absorption following cutaneous application of heparinoid (mucopolysaccharide polysulphate) have shown that between 0.3 and 4% of the mucopolysaccharide administered is absorbed by various tissues (other than the treated area) within the first 8 hours. Typically between 1.7% and 4.6% will be absorbed within 2 to 4 days. Animal studies have also shown that mucopolysaccharide is bound intracellularly within the subcutis. Peak serum concentrations following cutaneous application are below the threshold of physiological relevance for coagulation. Mucopolysaccharide is excreted in the urine partly unchanged and partly as depolymerized, shorter chain length molecules.

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

None stated

### **6. PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Isopropyl alcohol  
Polyacrylic acid  
Propylene glycol  
Purified water  
Sodium hydroxide

**6.2 Incompatibilities**

None.

**6.3 Shelf life**

5 years.

**6.4 Special precautions for storage**

Store below 25°C.

**6.5 Nature and contents of container**

Lacquered aluminium tubes 14, 50, 50g.

**6.6 Instructions for use, handling and disposal**

Not applicable.

**7 MARKETING AUTHORISATION HOLDER**

Genus Pharmaceuticals Limited  
T/A Genus Pharmaceuticals  
Linthwaite,  
Huddersfield,  
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**8. MARKETING AUTHORISATION NUMBER**

MA085/00102

**9. DATE OF THE FIRST AUTHORISATION OR RENEWAL**

30/08/2005

**10      DATE OF REVISION OF THE TEXT**

July 2016