SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hirudoid Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Heparinoid 0.3% *wlw* (Equivalent to 25 000 Units per 100 g cream).

Excipient(s) with known effect

Anhydrous eucerine (contains lanolin)	7.515% w/w
Cetostearyl alcohol	3.105% w/w
Methyl parahydroxybenzoate	0.16% w/w
Propyl parahydroxybenzoate	0.04% w/w

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Topical cream.

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 up to four times daily to the affected area and gently massaged into the skin.

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.

Instruct patients not to smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Ingredients with specified warnings

This product contains Cetostearyl alcohol and lanolin which may cause local skin reactions (e.g. contact dermatitis).

This product contains propyl parahydroxybenzoate and ethyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

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_2 synthesis and an indirect effect on LTB_4 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

Anhydrous eucerine (contains lanolin)
Emulsifying cetostearyl alcohol type A
Glycerol
Isopropyl alcohol
Methyl parahydroxybenzoate (E218)
Myristyl alcohol
Potassium hydroxide
Propyl parahydroxybenzoate (E216)
Purified water
Stearic acid
Thymol

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, 40, 50g.

6.6 Instructions for use, handling and disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Genus Pharmaceuticals Limited

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8. MARKETING AUTHORISATION NUMBER

PL 06831/0175

9. DATE OF THE FIRST AUTHORISATION OR RENEWAL

02/02/2006

10 DATE OF REVISION OF THE TEXT

04/12/2019