Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lasonil 0.8 % w/w Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100g of ointment contains heparinoid 5000 HDB-U (Heparinoid Bayer Units) equivalent to 0.8 % w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Ointment
Yellow ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

The topical management of traumatic conditions, e.g. bruises, sprains and soft tissue injuries.

4.2 Posology and method of administration

Lasonil should be applied thickly and gently massaged into the affected area two or three times daily. There is no special dosage for children.

4.3 Contraindications

The ointment is contraindicated for use in patients with known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Lasonil should be applied to unbroken skin only. Lasonil should not be applied to open or infected wounds or ulcers.

A physician should be consulted if symptoms persist.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent use of this product with systemically administered anticoagulants may lead to further prolongation of prothrombin time.

4.6 Pregnancy and lactation

There is no evidence to suggest that Lasonil should not be used during pregnancy and lactation. However, it should be used with caution during the first trimester.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Very rarely (<1/10,000) erythema and hypersensitivity reactions occur which subside when treatment with the ointment is stopped.

4.9 Overdose

In the unlikely event of Lasonil being taken orally, treat symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Heparinoid has been shown to prolong blood-clotting time locally and has an anti-inflammatory effect.

ATC code: C05BA, antivaricose therapy.

5.2 Pharmacokinetic properties

Heparinoids have a half-life of 2-6 hours after intravenous administration. There is no definitive evidence to date that heparins or heparinoids are absorbed after oral administration.

The transdermal absorption under intact anatomical conditions is between 1% and 2%. The transdermal absorption of high-dose heparinoids has been demonstrated by detecting their anticoagulant activities in both intact and surface-modified skin preparations (skin without epidermis) from various animals to man. Topical effects are assessed by measuring the influence of the substances on oedemas and haematomas.

The recalcification time and the thrombin time in blood were significantly prolonged after topical application of the heparinoid ointment to human subjects.

The anticoagulant effect was seen about 2 hours after application of the ointment. It reached a peak after 5 hours and remained detectable for 8 hours.

The absorption rate of radio-labelled heparinoid in guinea-pigs following depilation of the skin was over 33% after 10 hours.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to the information included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Wool alcohols
White soft paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Aluminium tube with an inner protective layer and screw-on cap enclosed in a cardboard outer carton. Sizes available are 14 g, 20 g and 40 g.

Not all pack sizes may be marketed.

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

Bayer plc
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Strawberry Hill, Newbury
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United Kingdom

Trading as Bayer PLC, Consumer Care Division

8 MARKETING AUTHORISATION NUMBER

PA 21/16/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 July 1983

Date of last renewal: 22 July 2003

10 DATE OF REVISION OF THE TEXT

August 2005