

## **Package leaflet: information for the user**

**Lioton gel 100 000**

**1 000 IU/g gel**

sodium salt of heparin

### **Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told to you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

### **What is in this leaflet:**

1. What Lioton gel 100 000 is and what it is used for
2. What you need to know before you take Lioton gel 100 000
3. How to use Lioton gel 100 000
4. Possible side effects
5. How to store Lioton gel 100 000
6. Contents of the pack and other information

## **1. What Lioton gel 100 000 is and what it is used for**

Lioton gel 100 000 is a dermal (skin) gel which contains active substance heparin in the form of heparin sodium salt. It belongs to a group of medicines for diseases of veins, and is also suitable for treating of inflammatory or accident conditions.

It is used for treatment of:

- superficial diseases of blood vessels, such as syndromes related to varicose veins (varicose syndromes) and complication associated with them, deep venous inflammation (phlebothrombosis), superficial periphlebitis (thrombophlebitis), inflammation of the vein wall or around the vein (superficial periphlebitis), crural ulcer,
- postoperative inflammation of varicose veins (postoperative varicophlebitis), conditions following operative removal of superficial subcutaneous veins of the lower limbs (saphenectomy),
- injuries and bruising (hematoma), local swellings and infiltrates (tissues with fluid accumulation), subcutaneous blood bruises,
- injuries of muscular-tendinous and capsular-ligamentous system.

After application the gel penetrates through the skin and has anti-edema, anti-inflammatory, anti-exudation and reduce blood clotting.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

## **2. What you need to know before you use Lioton gel 100 000**

**Do not use Lioton gel 100 000**

- if you are allergic to heparin sodium salt or any of the other ingredients of this medicine (listed in section 6).

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Lioton gel 100 000.

- If you have bleeding disorders, the doctor will decide whether you will be able to use this medicinal product or not.
- Lioton gel 100 000 should not be used in case of bleeding, to opened skin injuries and mucous membrane, nor infections areas in purulent processes.

### **Children**

Due to the limited experiences with this medicinal product in children, it should not be used in children.

### **Other medicines and Lioton gel 100 000**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. In patients who are taking medicines which reduce blood clotting (oral anticoagulants) may heparin, contained in this medicine, to prolong prothrombine time (the time it takes for blood clotting occurs), it will be reflected delayed blood clotting.

### **Pregnancy, breast feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Information about use of this medicinal product during pregnancy and breast feeding are not available.

### **Driving and using machines**

Lioton gel 100 000 has no effect on the ability to drive vehicles or use machines.

### **Lioton gel 100 000 contains:**

- **Methyl parahydroxybenzoate (E 218) and propyl parahydroxybenzoate (E 216)** as conservatives. They may cause allergic reactions (possibly delayed).
- Neroli fragrance and Lavandula intermedia oil (lavandin). They contain **citral, citronellol, coumarin, d-limonene, farnesol, geraniol and linalool**, which may cause allergic reactions.
- **Ethanol**. This medicine contains 233 mg ethanol (alcohol) in each g of gel. Ethanol may cause burning sensation on damaged skin.

## **3. How to use Lioton gel 100 000**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is apply 3 to 10 cm of gel one to three times daily to treated area and gently embrocate to facilitate its absorption.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

### **Use in children**

This medicinal product should not be used in children based on the limited experiences in children.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions to heparin following an application on the skin are very rare. However, rarely hypersensitivity reaction characterized by erythema and pruritus can occur, symptoms usually disappear following application discontinuation.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Lioton gel 100 000**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the carton and tube after EXP. The expiry date refers to the last day of that month.

Store below 25 °C.

Do not throw away any medicines via wastewater or household waste. Unused medicine return to the pharmacy. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Lioton gel 100 000 contains**

- The active substance is sodium salt of heparin. 1 g of gel contains 1 000 IU (International Units) of sodium heparin.
- The excipients are carbomerum, ethanol 96%, methyl parahydroxybenzoate (E 218) and propyl parahydroxybenzoate (E 216), Neroli fragrance (containing linalool, d-limonene, geraniol, citral, citronellol and farnesol), Lavandula intermedia oil (lavandin) (containing linalool, d-limonene, geraniol and coumarin), trolamine, purified water.

### **What Lioton gel 100 000 looks like and contents of the pack**

- Lioton gel is colourless, almost transparent gel in aluminium tube with internally coated with lack with polyethylene screw cap.
- Pack size: 30 g, 50 g or 100 g of gel in tube.  
Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

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