

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lioton 1000

Gel, 1000 IU / g

HEPARIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What LIOTON 1000 is and what it is used for
2. Before you take LIOTON 1000
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1. WHAT LIOTON 1000 IS AND WHAT IT IS USED FOR

Lioton 1000 gel is a mixture of heparin in gel form for external use. It is used alone or in combination with the systemic therapy of pathological, traumatic or inflammatory disorders to which the preparation shows favorable percutaneous antiexudative (decrease in permeability of the blood vessels), anti-endemic (reduces swelling), and soothing and anticoagulant effect.

Lioton 1000 gel therefore covers a wide and specific field of application, mainly in the field of venous inflammatory pathology referring to the internal medicine and vascular surgery, and in Traumatology-orthopedic field.

Lioton 1000 gel is characterized as very well tolerated, either locally or generally.

Lioton 1000 gel is used to treat diseases of the superficial veins, such as varicose syndromes and their complications, phlebothrombosis (clot formation in the deep veins), thrombophlebitis (vein inflammation caused by injury or infection), surface Periphlebitis (inflammation of the tissue around the vein), varicose ulcers (varicose veins in the skin that cause the occurrence of ulcers or wounds); Postoperative varicophlebitis; sequelae of saphenectomy. Traumas and contusions; infiltrates and local edemas; subcutaneous hematoma. Traumas and sprains of the musculotendinous and capsuloligamentous apparatuses.

2. BEFORE YOU TAKE LIOTON 1000

Do not take LIOTON 1000

If you are allergic (hypersensitive) to heparin or any other ingredient of this medicine.

Take special care with LIOTON 1000 if you

The use of Lioton 1000 gel in the presence of hemorrhages should be closely evaluated. Lioton 1000 gel should not be applied in cases of bleeding, open wounds or mucosae, nor on infection sites in case of suppurative processes.

Lioton 1000 gel contains the excipients methyl and propyl p-hydroxybenzoate and must not be used in patients with paraben allergies.

Taking other medicines

The use of heparin can further prolong prothrombin time in patients treated with oral anticoagulants.

Pregnancy and breast-feeding

No specific data exist on the use of the medicinal product during pregnancy and lactation.

Driving and using machines

LIOTON 1000 should not affect your ability to drive and use machines.

3. HOW TO TAKE LIOTON 1000

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

One to three applications a day, by gently applying 3 – 10 cm of gel to the affected area. Due to the limited experience and to the available data, it should not be used in children.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Allergic reactions to heparin on application to the skin are very rare. However, hypersensitivity reactions such as reddening of the skin and itching, which usually disappear rapidly following withdrawal of the preparation, may occur in isolated cases.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE LIOTON 1000

Keep out of the reach and sight of children.

Shelf life: Five years

Special precautions for storage: No special storage conditions.

6. FURTHER INFORMATION

What LIOTON 1000 contains

100 g of gel contains:

The active substance is heparin sodium

Other ingredients: Carbomer 940, methyl p-hydroxybenzoate, propyl p-hydroxybenzoate, ethyl alcohol, orange flower oil (neroli oil), lavender oil, triethanolamine, purified water

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

Berlin-Chemie AG (Menarini Group)
Glienicke Weg 125, Berlin, Germany

The manufacturer of the medicinal product

A. Menarini Manufacturing Logistics and Services SRL
Via Sette Santi 3, Florence, Italy