

PATIENT INFORMATION LEAFLET

Lioton® 1000 IU/g gel

Active substance: heparin sodium

Read all of this leaflet carefully before you start using 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 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.

What is in this leaflet

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

1. What Lioton gel is and what it is used for

Lioton gel contains as active principle heparin sodium in high concentration. Heparin has a local antithrombotic action, has blood circulation improving properties and eliminates swellings. This results in a quick pain relief. It penetrates quickly into skin and supports lasting the healing process in the sickened tissue.

Lioton gel can be used for supportive treatment in acute swelling conditions, after blunt injuries such as contusions or sport injuries as well as in superficial venous affections provided that it is not possible to treat it with compressions.

2. What you need to know before you use Lioton gel

Do not use Lioton gel,

- if you are allergic to heparin 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.

If the complains persist or if the expected success of therapy fails, medical advice is required as soon as possible. In the case of suspected phlebitis (venous inflammation) a physician should always be consulted.

Lioton gel should not be applied on open wounds or weeping eczemas.

Areas of eyes, nose and mouth have to be excluded from treatment.

Please inform your doctor if side effects occur and if you get pregnant.

No tolerance effects are known.

Children and adolescents

No interaction studies have been performed. Therefore, the use in paediatric population is not recommended.

Other medicines and Lioton gel

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. When used on large areas or at concomitant treatment with anticoagulant products (e.g. anticoagulants, acetyl salicylic acid) the bleeding tendency may be increased.

Pregnancy and breast-feeding

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.

Driving and using machines

Lioton gel has no or negligible influence on the ability to drive and use machines.

Lioton gel contains ethanol.

This medicine contains 233 mg alcohol (ethanol) in each g of gel. Ethanol may cause burning sensation on damaged skin.

Lioton gel contains methyl-4-hydroxybenzoate, propyl-4-hydroxybenzoate, neroli fragrance and lavender oil.

This medicine contains methyl-4-hydroxybenzoate and propyl-4-hydroxybenzoate as conservatives. They may cause allergic reactions (possibly delayed).

This medicine contains fragrances with citral, citronellol, coumarin, d-limonene, farnesol, geraniol and linalool. Citral, citronellol, coumarin, d-limonene, farnesol, geraniol and linalool may cause allergic reactions.

3. How to use Lioton gel

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.

The recommended dose is two to three times daily 10 cm of gel applied to the affected area and massaged gently until gel disappears.

In the case of acute swelling conditions after blunt injuries treatment duration up to ten days, in the case of superficial venous affections of about 1 to 2 weeks is recommended.

Use in children and adolescents

No interaction studies have been performed. Therefore, the use in paediatric population is not recommended.

If you use more Lioton gel than you should

If the amount of gel applied is too big, remove it with a cloth and/or wash the affected areas of the skin. Symptoms of poisoning are barely to be expected.

If you forget to use Lioton gel

Do not use a double dose to make up for a forgotten dose but just continue with the next scheduled dose.

If you stop using Lioton gel

For treatment success, regular and continuous use of Lioton gel is necessary.

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.

Stop treatment with Lioton gel and tell your doctor if you have an allergic reaction with symptoms like mild reddening of the skin and itching. These cases only appear in isolated cases.

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lioton gel

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

Store below 30°C.

In-use stability of this medicine is 24 weeks after first opening.

3 years in the intact packaging.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What Lioton gel contains**

- The active substance is Heparin sodium.
- The other ingredients are: purified water, ethanol 96%, Carbomer, trolamine, neroli fragrance (containing linalool, d-limonene, geraniol, citral, citronellol and farnesol), lavandin oil (containing linalool, d-limonene, geraniol and coumarin), methyl-4-hydroxybenzoate (E218) and propyl-4-hydroxybenzoate (E216) as conservatives.

What Lioton gel looks like and contents of the pack

Lioton gel is a colourless, almost transparent gel with an aromatic odour.

Lioton gel is available in a tube with 15 g, 30 g and 50 g gel.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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