

PACKAGE LEAFLET: INFORMATION FOR THE USER

BOSTROMBIN

(500 IU + 2.5 mg + 2.5 mg) / g Gel

SODIUM HEPARIN, DEXPANTHENOL, ALLANTOIN

• 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 BOSTROMBIN is and what it is used for
2. Before you take BOSTROMBIN
3. How to use BOSTROMBIN
4. Possible side effects
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1. WHAT BOSTROMBIN IS AND WHAT IT IS USED FOR

BOSTROMBIN gel contains three active ingredients, sodium heparin, dexpantenol and allantoin, and their activities complement each other. BOSTROMBIN gel belongs to the group of medicines known as anti-varicose therapy.

BOSTROMBIN gel is applied as a topical treatment for:

- Surface thrombophlebitis (localized inflammation of the superficial veins and the situation created as a result of thrombosis of superficial veins);
- Surface soft tissue injury resulting from blunt trauma (bruising, hematoma, contusions, etc.).

2. BEFORE YOU TAKE BOSTROMBIN

Do not take BOSTROMBIN

- If you are allergic (hypersensitive) to any ingredient of this medicine.
- If you have a lower leg ulcers (open vein wounds on the lower leg) which are bleeding or other bleeding in the skin;

- If you have open and / or infected wounds.

Do not use BOSTROMBIN gel if any of the above applies to you. If you are unsure, check with your doctor or pharmacist before taking this medicine.

Take special care with BOSTROMBIN

Due to the higher permeability of the skin, BOSTROMBIN gel should not be used in neonates and infants.

When applying BOSTROMBIN gel, be careful not to get in the eyes, on mucous membranes or open wounds, or on skin affected by infection.

If you have questions or concerns related to these precautions, please consult your doctor or pharmacist before using this medicine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription and herbal medicines.

Interactions with other medicines and other forms of interaction are not recorded.

BOSTROMBIN gel should not be used with other medicines intended for dermal administration (application to the skin).

Pregnancy and breast-feeding

Before you start using some medicine, consult your doctor or pharmacist.

There were no adverse effects on the mother and / or child, after local application of heparin sodium, dexpanthenol and allantoin.

Pregnant and breastfeeding women can apply BOSTROMBIN gel, as recommended in the proposed instruction.

Driving and using machines

BOSTROMBIN should not affect your ability to drive and use machines.

3. HOW TO TAKE BOSTROMBIN

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.

Method of administration

BOSTROMBIN gel is applied dermally (on the skin).

Dosage

BOSTROMBIN gel is applied to the affected area 2-4 times a day in a thin layer, without rubbing it into the skin.

If necessary, the surface can be covered with gauze and wrapped.

The duration of treatment depends on the indication, usually 1-2 weeks, and in chronic cases even longer.

Prolonged application of the gel should be under medical supervision.

If you use more BOSTROMBIN gel than you should

If you use a greater amount of medicine than prescribed, immediately contact your doctor or pharmacist!

Overdose with BOSTROMBIN gel is not recorded.

If the gel is applied as recommended, there is no risk of overdose.

If you forget to use BOSTROMBIN gel

If you forget to use the medicine, do not apply a double amount of the medicine later, but continue using the medicine as usual.

Besides this, there are no additional notes.

If you stop using BOSTROMBIN gel

Use this medicine as long as your doctor has prescribed.

If you suddenly stop using BOSTROMBIN gel, do not expect negative consequences. If you have concerns, talk to your doctor or pharmacist before discontinuation of treatment with BOSTROMBIN gel.

4. POSSIBLE SIDE EFFECTS

Allergic reactions to BOSTROMBIN gel are very rare. During long-term dermal application it may cause skin sensitization (itching, redness, burning sensation). In this case, the application of the gel should be discontinued.

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.

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

5. HOW TO STORE BOSTROMBIN

Keep out of the reach and sight of children.

Do not use BOSTROMBIN after the expiry date which is stated on the label, 2 years from the date of manufacture.

6. FURTHER INFORMATION

What BOSTROMBIN contains

1 g of gel contains: heparin sodium 500 I.U.
dexpanthenol 2.50 mg
allantoin 2.50 mg

BOSTROMBIN gel contains the following excipients: isopropyl alcohol, bactericide MB, carbomer, triethanolamine, sorbitol non-crystalline (E420), polysorbate 80 (E433), pine needles oil, racemic menthol and purified water.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosna i Hercegovina