

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sinedol

(500 I.U. + 150mg + 25 mg) / g gel

HEPARIN, DIMETHYLSULFOXIDE, DEXPANTHENOL

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

Sinedol gel is a preparation which includes heparin sodium, dimethyl sulfoxide and dexpanthenol. It is intended for the treatment of sports injuries and other injuries of muscles, tendons and joints caused by blunt force. It is also used in the treatment of peripheral veins, as well as neuropathic pain and acute inflammation in the region of the shoulder joint.

How Sinedol works?

The medicine Sinedol gel prevents coagulation (clotting) of blood in sports and other injuries. Other active substances in the preparation are dimethylsulfoxide and dexpanthenol. Dimethylsulfoxide allows faster penetration of heparin through the skin and thus enhances its action, and it is also effective against inflammation, pain and swelling of tissue. Dexpanthenol helps the healing and regeneration (recovery) of damaged skin.

When is Sinedol used?

Sinedol is used at sports and other injuries (such as bruises, sprains and strains) and diseases such as bursitis and tendovaginitis (inflammation of the tendon sheath). Also, Sinedol gel can also be used for disorders of the peripheral veins, such as thrombophlebitis (veins inflammation associated with thrombus formation), varicose

veins, and the consequential changes in the skin, as well as neuropathic pain and acute inflammation in the shoulder joint region.

2. BEFORE YOU TAKE SINEDOL

Do not take SINEDOL

- If you are allergic (hypersensitive) to heparin, dimethyl sulfoxide, dexpanthenol or the other ingredients in the preparation
- If you suffer from bronchial asthma
- If you are pregnant or breast-feeding
- If you have liver or kidney damage regardless of the cause
- If you have lupus erythematosus (a disease of the skin)
- Medicine should not be given to children under the age of 5 years.

Take special care with SINEDOL

This medicine is not recommended for use on open wounds.

The occurrence of allergic skin reactions requires discontinuation of therapy.

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.

Sinedol gel should not be used simultaneously with sulindac, anti-inflammatory drug that belongs to a group of anti-rheumatics.

Before using Sinedol gel, consult your doctor if you are using some of the products that are applied to the skin. No other medication should be applied to the skin surface immediately before or after applying the gel Sinedol.

Pregnancy and breast-feeding

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

Sinedol gel cannot be used during pregnancy and breast-feeding.

Driving and using machines

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

3. HOW TO TAKE SINEDOL

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.

Sinedol gel is applied twice daily to the affected area in a thin layer without rubbing it in. After application of the gel, the skin surface should not be covered with a bandage.

The skin must be dry and clean before applying Sinedol gel.

If you use more SINEDOL gel than you should

If you have taken a larger dose than recommended, or if someone else accidentally took your medicine, immediately contact your doctor, pharmacist or nearest hospital!

If you forget to use SINEDOL gel

Do not use a double dose to make up for the forgotten dose.

If you miss a dose, apply the next dose at the usual time and continue to use the medicine as instructed by a doctor.

4. POSSIBLE SIDE EFFECTS

Allergic reactions to SINEDOL gel are very rare.

There are cases of gastrointestinal side effects, such as nausea, vomiting, diarrhea, constipation and loss of appetite.

In individual cases, there have been hypersensitivity reactions such as urticaria and angioneurotic edema (sudden emergence of localized swelling that usually affects the face or neck).

Heparin can cause thrombocytopenia (reduced blood platelet counts). The risk of bleeding is increased in people who consume large amounts of alcohol.

When applied to the skin, especially in high concentrations, Dimethylsulfoxide can cause inflammation, tingling, itching, erythema (redness), hives and blistering; during the next application, these reactions are usually absent. Regardless of the route of administration, dimethyl can cause a short-term change in the sense of taste, the smell of the garlic (which disappears after a few minutes) and allergic sensitization.

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 SINEDOL

Keep out of the reach and sight of children.

Do not use SINEDOL after the expiry date which is stated on the label, 5 years from the date of manufacture. Any unused medicine is destroyed in accordance with applicable regulations.

6. FURTHER INFORMATION

What SINEDOL contains

The active substances are:

1 g of gel contains:

Heparin sodium 500 I.U.

Dimethylsulfoxide 150 mg

Dexpanthenol 25 mg

Excipients are:

Isopropyl alcohol, carbomer 940, hydrogenated castor oil, trolamine, essential oil of mountain pine, rosemary essential oil, lemon essential oil, purified water.

Homogeneous, clear, colorless gel with a characteristic odor.

Tube with 40 g of gel.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

Hemofarm d.o.o. Banja Luka

Novakovići bb, Banja Luka, BiH