# HEPARINE MEDIS® 25000 I.U/5ml

# HEPARIN SODIUM 25000 IU INEJECTABLE SOLUTION B/10 VIALS/5ML

**Please read carefully the integrality of this notice before taking this drug.**
- Keep this notice; you may need to read it again.
- If you have further questions, if you have any doubt, ask your doctor or pharmacist for more information.
- This drug was prescribed for you personally. Never give it to someone else, even in case of identical symptoms; this could be harmful for this person.
- If one of the undesirable effects worsens or if you experience an undesirable effect which is not mentioned in this notice, inform your doctor or your pharmacist.

In this leaflet:


## 1. WHAT IS HEPARINE MEDIS® 25 000 IU/5 ml, injectable solution AND IN WHICH CASES IT IS USED?

Pharmacotherapeutic group:Antithrombotic / Heparin
This medication is an anticoagulant of the heparin family.
It is indicated for:
- PROPHYLAXIS AND TREATMENT OF THROMBOEMBOLIC DISEASES (PHLEBITIS AND THROMBOPHLEBITIS ET EMBOLISMS)
- AS AN ADJUVANT TO EARLY TREATMENT OF MYCOCARDIAL INFARCTUS
- HEPARINIZATION OF BLOOD IN EXTRACORPOREAL CIRCULATION OR DURING DIALYSIS.

## 2. WHAT INFORMATION SHOULD BE KNOWN BEFORE USING HEPARINE MEDIS® 25 000 IU/5 ml, injectable solution?

**Never use HEPARINE MEDIS® 25 000 IU/5 ml, injectable solution:**
- If you are allergic to the active substance (heparin sodium) or any of the other ingredients of HEPARINE MEDIS®. You will find the list of components in sectionsection 6.
- If you have ever had a severe episode of platelet reduction caused by heparin (platelets are important blood components for blood clotting).
- If you have a blood coagulation anomaly (with the exception of some coagulation diseases that are treated with HEPARINE MEDIS®).
- If you have a lesion (internal or external) that may bleed.
- If you have bleeding in the brain (cerebral hemorrhage).
- In premature infants and newborns as this drug contains chlorocresol.

Epidural anesthesia and spinal anesthesia (anesthesia via the spine) should never be performed during treatment with HEPARINE MEDIS®

**Use of this medication is not recommended:**
- In the first 3 days after a stroke without bleeding (non haemorrhagic cerebrovascular accident).
- If you have high blood pressure despite the use of a treatment (hypertension not controlled by the treatment).
- If you suffer from endocarditis (inflammation of the heart valves or the walls of the heart chambers which can lead to serious heart failure).
- If you are taking certain medicines at the same time (see "Taking other medicines").

**Take special care with HEPARINE MEDIS® 25 000 IU/5 ml injectable solution:**
This treatment requires repeated blood tests to regularly check the number of your platelets (usually twice a week). Indeed, very rarely, a significant reduction in the number of platelets can occur during the treatment with heparin. This necessitates a discontinuation of heparin and increased monitoring as serious complications can occur, including thrombosis.
Do not inject this medication into a muscle (intramuscular). The injection procedures must be strictly followed(see also sectionsection 3).
This medication contains chlorocresol and may cause allergic reactions.
Tell your doctor:
- if you have had a digestive ulcer,
- if you have a retinal disease,
- if you have just undergone an operation of the brain or spinal cord,
- if you have to undergo lumbar puncture (lower back sampling).

These situations may require special monitoring such as medical examinations and blood tests.
*If you have to undergo an operation:*
Tell your doctor, surgeon, anesthesiologist or dentist if you are taking this medication, even if it is a minor surgical procedure.

**Taking other medicines**
Due to the possible occurrence of bleeding, systematically tell your doctor if you are taking any of these medicines at the same time:
- aspirin at doses used for pain and fever,
- a non-steroidal anti-inflammatory drug used for pain, fever or rheumatism,
- dextran (used in intensive care).

The use of these medicines is not recommended if you are using HEPARINE MEDIS®.
You should also tell your doctor if you take:
- a glucocorticoid (a medicine used to treat a rheumatic disease, pain or inflammation),
- a platelet antiaggregant used to thin the blood (such as low-dose aspirin, ticlopidine, clopidogrel, platelet GPIIb/IIIa receptor antagonists, dipyridamole)
- medicines used to prevent or treat blood clots (thrombolytics).

If you are taking or have recently taken any other medications, including medications obtained without a prescription, talk to your doctor or pharmacist.
Your doctor will be able to adjust your treatment accordingly.

**Pregnancy**
Ask your doctor or pharmacist for advice before taking any medicine
In case of need, your doctor may prescribe this medicine during pregnancy.
If you use this medication during pregnancy, epidural anesthesia (anesthesia via the spine), especially at the time of delivery, should never be practiced.
If you discover that you are pregnant during treatment, consult your doctor as he alone can judge the necessity to continue it.

**Lactation**
Ask your doctor or pharmacist for advice before taking any medication.
This medication can be used if you are breastfeeding.

**List of excipients with known effect:**
This medicine contains chlorocresol and may cause allergic reactions.

## 3. HOW TO USE HEPARINE MEDIS® 25 000 IU/5 ml, injectable solution?

**Dosage**
**In curative treatment, in prevention of arterial thromboembolic events in the case of emboligenic cardiopathy:**
Diagram for recommended dosage regimen excluding coagulopathy:
Heparin should be administered in continuous injection with an electric syringe.
A bolus of 50 IU/kg can be administered beforehand by direct intravenous administration to achieve effective heparinemia at the start of treatment.
The initial dose is 20 IU/kg/h.
The dose of heparin will then be adjusted according to the results of the biological monitoring.
Coagulopathies :
The dose administered is generally lower due to the risk of haemorrhage.
Biological surveillance:
It must be at least daily. The 1st sampling must take place 6 hours after the start of treatment. A sample should be taken 4 to 6 hours after each dose modification.
It is possible to use, depending on the case:
- the activated partial thromboplastin time (APTT), which must be between 1.5 and 3 times the control according to the sensitivity of the reagent used (to be defined by the laboratory),
- the anti-Xa activity (heparinemia), which is a specific test. It should be between 0.2 and 0.6 IU/ml. This test will be preferred when there are pre-existing APTT abnormalities, inintensive care patients and in cases of a marked inflammatory syndrome.

Switch from heparin to oral anticoagulants:
Whenever this is possible, the oral anticoagulant will be introduced between the 1st and 3rd day of treatment, so that the total duration of heparin therapy will not exceed 7 to 10 days.
Due to the latency period preceding the full effect of the anti-vitamin K used, the heparin will only be interrupted when the INR is in the desirable therapeutic zone for 2 consecutive days. This is variable depending on the pathology treated.
During this period, surveillance of the APTT will be particularly careful to avoid a risk of bleeding.

**Prevention of arterial thromboembolic events in cases of endovascular therapy and arterial vascular surgery; Prevention of coagulation in extracorporeal and external purification circulation circuits:**
In these situations, dosage and biological monitoring will be determined according to each clinical situation.

**Method of administration**
Intravenous route.
Do not inject by intramuscular route.

**If you take more HEPARINE MEDIS® 25,000 IU/5 ml, injectable solution than you should:**
The occurrence of bleeding may be a sign of overdose: in this case, promptly notify the healthcare staff.
Neutralization of heparin may be accomplished by intravenous injection of a suitable dose of protamine.

## 4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

Like all medicines, this medicine may cause side effects, but they do not occur systematically in all subjects.

**The following side effects occur very frequently ( more than 1 in 10 people ):**
- Bleeding can be severe, visible or not, some of which can be life threatening. These bleedings may be increased if you have a lesion that is likely to bleed, if you have kidney failure, or if you are taking certain medications at the same time. Your doctor or nurse should be notified immediately.

**The following side effects occur frequently ( 1 to 10 people out of 100 ):**
- Moderate and early decline in the number of platelets in the blood (thrombocytopenia).
- Increased levels of certain liver enzymes.

**The following side effects occur infrequently ( 1 to 10 people out of 1,000):**
- Local or general allergic reactions. You will recognize an allergic reaction by the occurrence of any of the following signs: rash on the skin, itching, purplish skin, inflammation of the conjunctiva (conjunctivitis), inflammation of the nose (rhinitis), asthma, acceleration of respiratory rate, feeling of oppression, fever, chills, swelling of the face and tongue. If any of these effects occur, you should stop treatment and report it immediately to your treating doctor.

**The following side effects occur rarely ( 1 to 10 people out of 10,000):**
- Serious allergic reaction with sudden discomfort and severe drop in blood pressure, which may be preceded by an eruption of pimples, itching, redness on the skin (anaphylactic shock). In this case, you should stop treatment and report it immediately to your treating doctor.
- Severe skin reactions (necrosis) at or near the injection sites, which may be preceded by small painful red patches on the skin (purpura). This should cause the treatment to stop immediately.
- Increased levels of certain white blood cells (eosinophils) sometimes associated with rash of the skin.
- Significant decrease in the number of platelets in the blood, which can be life-threatening. In this case, your doctor should be notified immediately. Therefore, the number of platelets should be checked regularly.

**The following side effects occur very rarely ( less than 1 in 10,000 people):**
- Bleeding at the spinal level, when administered during anesthesia performed via the spine or in a lumbar puncture (sampling from the lower back). Epidural anesthesia and spinal anesthesia (anesthesia via the spine) should never be performed during treatment with HEPARINE MEDIS® (see sectionsection 2).
- Biological anomalies (when taking blood), especially if you have diabetes or if you have kidney failure:
  * decreased aldosterone level, manifesting as low blood pressure, dehydration, with:
- an increase in the level of potassium in the blood,
- a decrease in the level of sodium in the blood,
- an increase in acidity in the blood (metabolic acidosis).
  * hair loss..
  * prolonged painful erection.

Osteoporosis (demineralization of the skeleton leading to bone fragility) during prolonged treatment.
If you experience any side effects, talk to your doctor or pharmacist. This also applies to any side effects not mentioned in this leaflet.

## 5. HOW TO STORE HEPARINE MEDIS® 25 000 IU/5 ml, injectable solution?

Keep out of the reach and sight of children.
Do not use HEPARINE MEDIS® 25 000 IU/5 ml, injectable solution after the expiry date which is stated on the box.
Store at a temperature not exceeding 25 ° C.
Medicines should not at all be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. ADDITIONAL INFORMATION

**What does HEPARINE MEDIS® 25,000 IU/5 ml, injectable solution contain?**
- The active substance is Heparin Sodium. Each vial of 5 ml of solution for infusion contains 25 000 IU heparin sodium.
- The other ingredients are Chlorocresol and Water for injections.

**What is HEPARINE MEDIS® 25 000 IU/5 ml, injectable solution and contents of the outer packaging:**
This medication is in the form of an injectable solution in a glass vial. Box of 10 vials of 5 ml.
**Marketing Authorisation N°:** 923 318 1
**Delivery conditions:**
List I (Table A).
**Marketing authorization holder and manufacturer:**
Les Laboratoires MédiS
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**This is a drug**
- A drug is a product but it is different from the other products.
- A drug is a product which acts on your health and its non appropriate consumption can expose you to danger.
- Rigorously respect your doctor's prescription and the mode of administration he prescribed. Follow your pharmacist's advices.
- Your doctor and your pharmacist know drugs, their indications and contra-indications.
- Do not stop on your own initiative the treatment during the prescribed period
- Do not retake, do not increase doses without consulting your doctor.

**Keep any drug out of the reach of children**


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