

# HEPARINE MEDIS® 25 000 IU/5 ml, solution for injection Heparin sodium

**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 your 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. See section 4.

## What is in this leaflet?

1. what is HEPARINE MEDIS 25 000 IU/5 ml, solution for injection and in which case is it used?
2. what you need to know before you take HEPARINE MEDIS 25 000 IU/5 ml, solution for injection?
3. how to take HEPARINE MEDIS 25 000 IU/5 ml, solution for injection?
4. possible side effects?
5. how to store HEPARINE MEDIS 25 000 IU/5 ml, solution for injection?
6. Content of the packaging and other information.

## 1. WHAT IS HEPARINE MEDIS 25 000 IU/5 ml, solution for injection AND IN WHICH CASE IS IT USED?

Pharmacotherapeutic group: Antithrombotic / heparin - ATC code: B01AB01

This medicine is an anticoagulant of the heparin family.

This medicine is used as a curative treatment to treat:

· A clot in a vein (venous thrombosis, also called phlebitis) or a clot in an artery in the lung (pulmonary embolism).

· A myocardial infarction or a severe form of angina pectoris (coronary artery disease recognizable by pain in the chest).

· A clot that forms in an artery outside the brain (extracerebral arterial embolism).

· Certain diseases of blood clotting.

This medicine is also used as a preventive treatment to avoid:

· The formation of a clot in an artery outside the brain (extracerebral arterial embolism).

· Blood clotting in the dialysis circuits, if you have severe kidney disease (renal failure) and are on dialysis.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE HEPARINE MEDIS 25 000 IU/5 ml, solution for injection?

**Never take HEPARINE MEDIS 25 000 IU/5 ml, solution for injection:**

· If you are allergic to Heparin sodium or any of the other components of this medicine, listed in section 6.

· If you have ever had a severe episode of low platelets caused by heparin (platelets are important parts of the blood for blood clotting).

· If you have any blood clotting abnormality (except for certain bleeding disorders which may require treatment 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 babies, term newborns and children under 3 years of age because this medicine contains benzyl alcohol.

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

**The use of this medicine is not recommended:**

· Within the first 3 days after a stroke without bleeding (non-hemorrhagic stroke).

· If you have high blood pressure despite using treatment (high blood pressure not controlled by treatment).

· If you have endocarditis (inflammation of the heart valves or the walls of the heart chambers which can lead to severe heart failure).

· If you are taking certain medicines at the same time (see "Other medicines and HEPARINE MEDIS 25 000 IU/5 ml, solution for injection").

## Warnings and precautions

Talk to your doctor or pharmacist before using HEPARINE MEDIS 25 000 IU/5 ml, solution for injection.

This treatment requires repeated blood tests to check your platelet count regularly (usually twice a week. In fact, very rarely, during treatment with heparin, a significant drop in the number of platelets may occur. This requires stopping heparin and increased monitoring because serious complications can occur, including thrombosis.

Do not inject this medicine into a muscle (intramuscularly). The injection procedures must be followed very precisely (see also section 3).

This medicine contains benzyl alcohol. There are heparin-based specialities without benzyl alcohol to be used preferentially in certain populations (see below and section Pregnancy and breastfeeding). Ask your doctor or pharmacist for advice if you have liver or kidney disease. Large amounts of benzyl alcohol can build up in your body and cause side effects (called "metabolic acidosis").

Benzyl alcohol can cause allergic reactions.

Benzyl alcohol is associated with a risk of serious side effects including breathing problems (called "suffocation syndrome" in young children (under 3 years). Fatal cases have been reported in premature and term newborns.

Tell your doctor:

· If you have had a digestive ulcer,

· If you have retinal disease,

· If you have just had brain or spinal cord surgery,

· If you are due to have a lumbar puncture (sample from the lower back).

These situations may require special monitoring such as medical examinations and blood tests.

If you are to have an operation:

Tell your doctor, surgeon, anesthesiologist or dentist about taking this medicine, in the event that surgery, even minor, is planned.

**Other medicines and HEPARINE MEDIS 25 000 IU/5 ml, solution for injection**

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. Your doctor may adapt the modalities of your treatment accordingly to the possible occurrence of bleeding, always tell your doctor if you are taking any of these medicines at the same time:

· aspirin at the doses used for inflammation, pain and fever,

· a nonsteroidal 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 as a curative treatment. You should also tell your doctor if you are taking:

· an oral anticoagulant (antivitamin K),

· aspirin (if you are using HEPARINE MEDIS for preventive treatment),

· a glucocorticoid (medicine used to treat rheumatic disease, pain or inflammation),

· a nonsteroidal anti-inflammatory drug used for pain, fever or rheumatism (if you are using HEPARINE MEDIS for preventive treatment),

· an antiplatelet agent used to thin the blood (such as low dose aspirin, ticlopidine, clopidogrel, platelet GPIIb / IIIa receptor antagonists, dipyridamole),

· medicines used to prevent or treat the formation of blood clots (thrombolytics),

· a medicine that increases the level of potassium in the blood.

**HEPARINE MEDIS 25 000 IU/5 ml, solution for injection with food and drinks**

Not applicable.

**Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

## Pregnancy

This medicine contains benzyl alcohol.

If you are pregnant, large amounts of benzyl alcohol can build up in your body and cause side effects (called "metabolic acidosis").

Benzyl alcohol crosses the placenta.

It is therefore recommended to use a presentation that does not contain benzyl alcohol if you are pregnant. If your doctor has nevertheless prescribed this medicine for you during your pregnancy, epidural anesthesia (anesthesia via the spine), especially at the time of childbirth, should never be performed.

If you discover that you are pregnant during treatment, consult your doctor as only he can judge the need to continue it.

## Breastfeeding

This medicine contains benzyl alcohol.

If you are breastfeeding, large amounts of benzyl alcohol can build up in your body and cause side effects (called "metabolic acidosis").

It is therefore recommended to use a presentation that does not contain benzyl alcohol if you are breastfeeding. Ask your doctor or pharmacist for advice if you are breastfeeding or planning to breastfeed.

## Driving and using machines

Not applicable.

**HEPARINE MEDIS 25 000 IU/5 ml, solution for injection contains sodium and benzyl alcohol.**

This medicine contains 17.71 mg sodium (main component of table / table salt) per 5 mL vial. This is equivalent to 1.25% of the recommended maximum daily dietary intake of sodium for an adult. The presence of sodium should be taken into account for a dose of HEPARINE MEDIS 25 000 IU/5 ml, solution for

injection greater than or equal to 23 000 IU, i.e. from a sodium dose of 23 mg (1 mmol). This should be taken into account, especially in patients controlling their dietary sodium intake.

This medicine contains 47.25 mg of benzyl alcohol per vial (see Warnings and precautions above, and Pregnancy and breastfeeding patients controlling their dietary sodium intake).

## 3. HOW TO TAKE HEPARINE MEDIS 25 000 IU/5 ml, solution for injection?

### Dosage

The dose and duration of treatment are determined by your doctor depending on your weight and the disease for which you are being treated.

### In curative treatment:

The usual dose is 20 IU/kg/hour, using an electric syringe. At the start of treatment, you may also be injected with a dose of heparin of 50 IU/kg by direct intravenous route.

The heparin dose will then be adjusted according to the results of the monitoring blood tests. When HEPARINE MEDIS is used to treat blood clotting disease, the dose given is usually lower.

In order to monitor your treatment, your doctor will perform blood tests such as:

· a measurement of your blood clotting time (TCA),

· a measurement of your heparin level in the blood (heparinemia).

If your doctor decides to replace heparin MEDIS with an oral anticoagulant:

· HEPARINE MEDIS injections will only be stopped after a few days during which you will take the 2 treatments at the same time.

· This is the time it takes for the second treatment to be active and for the coagulation blood tests to be at the level desired by your doctor.

### In preventive treatment:

Your doctor will decide on the dose, the number of injections and whether or not to monitor your blood tests depending on your case.

### Method of administration

· This medicine will be injected into a vein (intravenously), using an electric syringe.

· This medicine should never be injected into a muscle (intramuscular route).

### Duration of treatment

The duration of treatment is determined by your doctor and depends on the disease for which you are being treated. You must respect your doctor's prescription.

**If you have taken more HEPARINE MEDIS 25 000 IU/5 ml, solution for injection than you should**

Contact a doctor promptly, due to risk of bleeding.

**If you forget to use HEPARINE MEDIS 25 000 IU/5 ml, solution for injection:**

Not applicable.

If you stop taking HEPARINE MEDIS 25 000 IU/5 ml, solution for injection:

Not applicable.

## 4. POSSIBLE SIDE EFFECTS?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**The following side effects are very common (more than 1 in 10 people):**

· Bleeding which may be severe, visible or not, some of which can be life-threatening. This bleeding may be increased if you have a lesion that may bleed, if you have kidney failure, or if you are taking certain medicines at the same time. Tell your doctor or nurse immediately.

**The following side effects occur frequently (1 to 10 in 100 people):**

· Moderate and early drop in the number of platelets in the blood (thrombocytopenia).

· Increased levels of certain liver enzymes.

**The following side effects occur uncommonly (1 to 10 in 1 000 people):**

· Local or general allergic reactions. You will recognize an allergic reaction by the appearance of any of the following signs : signs: rash on the skin, itching, purplish skin, inflammation of the conjunctiva (conjunctivitis), inflammation of the nose (rhinitis), asthma, increased respiratory rate, feeling of tightness, fever, chills, swelling of the face and tongue. If any of these effects occur, you must stop treatment and report it immediately to your doctor.

**The following side effects occur rarely (1 to 10 in 10 000 people):**

· Serious skin reactions (necrosis) at or away from injection sites, which may be preceded by small, red, painful spots on the skin (purpura). This should cause the treatment to be stopped immediately.

· Increased levels of certain white blood cells (eosinophils) sometimes associated with a skin rash.

· Significant decrease in the number of platelets in the blood, which can be life-threatening. In this case, you should immediately notify your doctor. This is why the number of platelets should be checked regularly.

**The following side effects occur very rarely (less than 1 in 10 000 people):**

· Bleeding in the spine, when administered during anesthesia performed via the spine or during a lumbar puncture (sample from the lower back). Epidural anesthesia and spinal anesthesia (anesthesia via the spine) should never be performed during treatment with HEPARINE MEDIS (see section 2).

· Laboratory abnormalities (during blood test), especially if you have diabetes or have kidney failure:

o Decreased aldosterone levels, manifested by low blood pressure, dehydration, with:

§ An increase in the level of potassium in the blood,

§ Decreased sodium level in the blood,

§ An increase in acidity in the blood (metabolic acidosis).

o Hair loss.

o Prolonged painful erection.

**The following side effects occur with an unknown frequency:**

· Serious allergic reaction with sudden discomfort and significant drop in blood pressure, which may be preceded by a rash of pimples, itching, redness on the skin (anaphylactic shock). In this case, you must stop the treatment and report it immediately to your doctor.

· Osteoporosis (demineralization of the skeleton leading to bone fragility) during prolonged treatment.

## Reporting side effects

If you get any side effects talk to your doctor or pharmacist. This also applies to any side effects not mentioned in this leaflet. You can also report side effects directly via the national reporting system: CNPV (Centre National de Pharmacovigilance).

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

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

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

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

Store at a temperature not exceeding 25 ° C.

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

**6. CONTENT OF THE PACKAGING AND OTHER INFORMATION**

**What HEPARINE MEDIS 25 000 IU/5 ml, solution for injection contains**

The active substance is:

Heparin sodium..... 25 000 IU For a bottle of 5 ml.

The other components are: benzyl alcohol, sodium chloride, hydrochloric acid solution or sodium hydroxide solution, water for injections.

**What does HEPARINE MEDIS 25 000 IU/5 ml, solution for injection look like and content of the outer packaging**

This medicine is in the form of a solution for injection in a vial. Each box contains 10 vials.

**Dispensing Supply conditions:** Table A/List I

**Marketing authorisation number MA N°:** 9233181

**Marketing authorisation holder and Manufacturer**

Les Laboratoires MédiS.

Road of Tunis - KM 7 - BP 206 8000 Nabeul - Tunisia

Tel : +216 72 235 006 / Fax : +216 72 235 016

E-mail : contact@labomedis.com

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## INSTRUCTIONS FOR THE PERSON ADMINISTERING THIS MEDICINE

### Dosage

#### In curative treatment:

HEPARINE MEDIS must be administered as a continuous injection with an electric syringe.

· a dose of 50 IU/kg can be administered directly intravenously at the start of treatment,

· the heparin dose used for the first electric syringe is 20IU/kg/hour. It will then be modified according to the results of the monitoring blood tests,

· for coagulopathies, the dose administered is generally lower due to the risk of bleeding.

#### In preventive treatment:

The dosage and biological monitoring will be determined according to each clinical situation.

**If you have injected more HEPARINE MEDIS than you should**

Neutralization of heparin can optionally be achieved by intravenous injection of a suitable dose of protamine.

## This is a medicine

- A medicine is a product but not like any other product.
- A medicine is a product that affects your health, if it's not used properly : it can be health threatening.
- Strictly adhere to the prescription of your Doctor and the use instructions prescribed, follow your pharmacist advice.
- Your doctor and you pharmacist know the medicine, its use and side effect.
- Don't stop the use of the treatment on your own during the prescribed time.
- Don't retake, Don't increase the doses without doctor's advice.

**Keep the medicines out of reach of children**



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