Package leaflet: information for the user
Heparin Sodium ROVI 1,000 IU/mL solution for injection
heparin sodium

Read all of this leaflet carefully before you are given 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 nurse.
- 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 nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet:

1. What Heparin Sodium ROVI 1,000 IU/mL is and what it is used for
2. What you need to know before you are given Heparin Sodium ROVI 1,000 IU/mL solution for injection
3. How Heparin Sodium ROVI 1,000 IU/mL solution for injection is given
4. Possible side effects
5 How to store Heparin Sodium ROVI 1,000 IU/mL solution for injection
6. Contents of the pack and other information

1. What Heparin Sodium ROVI 1,000 IU/mL is and what it is used for

The name of this medicine is Heparin Sodium ROVI 1,000 IU/mL solution for injection (referred to as 'Heparin Sodium ROVI 1,000 IU/mL' in this leaflet). Heparin sodium belongs to a group of medicines called anticoagulants. Heparin prevents blood clotting.

This medicine is used to treat and prevent:
- Blood clots in leg veins (deep venous thrombosis)
- Blood clots in the lung (pulmonary thromboembolism)

as well as for:
- The treatment of chest pains resulting from disease of the heart arteries (unstable angina pectoris)
- The treatment of severe blockages affecting arteries in the legs (acute peripheral arterial occlusion)
- The prevention of blood clots following a heart attack (mural thrombosis).

It is also used during heart and lung operations and during kidney dialysis.

2. What you need to know before you are given Heparin Sodium ROVI 1,000 IU/mL solution for injection

You should not be given Heparin Sodium ROVI 1,000 IU/mL solution for injection if you:
- are allergic to heparin or any other ingredients of this medicine (listed in section 6),
- are pregnant,
- bleed or bruise easily,
- have had severe skin problems resulting from previous heparin treatment,
- are about to have surgery of the brain, spine or eye, a lumbar puncture or local anaesthetic nerve block or some other procedure where bleeding could be a problem.

Heparin Sodium ROVI 1,000 IU/mL solution for injection must not be given to premature or newborn babies or children up to 3 years of age.

Warnings and precautions
Talk to your doctor or nurse before receiving Heparin Sodium ROVI 1,000 IU/mL solution for injection. Particularly careful medical supervision is required if you:

- are over 60 years of age,
- have any condition which makes you likely to bleed more easily. If you are unsure ask your doctor or nurse,
- are diabetic,
- have high levels of potassium in the blood or if you take drugs that may increase the potassium level in your blood,
- have kidney or liver disease. Your doctor may decide that a lower dose is necessary,
- suffer from allergies or have previously had an allergic reaction to heparin.

Your doctor will check your blood if you receive treatment for longer than five days and may do other blood tests if you have major surgery.

Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

Children
Heparin Sodium ROVI 1,000 IU/mL must not be given to premature or newborn babies or children under 3 years of age.

Other medicines and Heparin Sodium ROVI 1,000 IU/mL solution for injection
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may affect the way heparin injection works. Taking some medicines at the same time as heparin may mean you may be likely to bleed more.

In particular, tell your doctor if you are taking any of the following medicines:
- Aspirin or other non-steroidal anti-inflammatory drugs (e.g diclofenac or ibuprofen),
- Medicines which may interfere with the proper clotting of the blood (e.g. dipyridamole, epoprostenol, clopidogrel or streptokinase),
- Medicines that may increase the potassium level in your blood,
- Glyceryl trinitrate (for heart disease).

If you need one of the above medicines your doctor may decide to alter the dose of heparin injection or the other medication.
If you have any doubts about whether this medicine should be administered then discuss things more fully with your doctor or nurse before Heparin Sodium ROVI 1,000 IU/mL is given.

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 nurse for advice before receiving this medicine. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").
You should not be given Heparin Sodium ROVI 1,000 IU/mL if you are pregnant.

Driving and using machines
Heparin Sodium ROVI 1,000 IU/mL solution for injection has not been reported to affect the ability to drive or operate machines.

Heparin Sodium ROVI 1,000 IU/mL contains benzyl alcohol
This medicine contains 10 mg/mL of benzyl alcohol in each mL.
Benzyl alcohol may cause allergic reactions. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gasping syndrome") in young children.

Heparin Sodium ROVI 1,000 IU/mL contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

3. How Heparin Sodium ROVI 1,000 IU/mL solution for injection is given

Your doctor or nurse will inject your dose of heparin into a vein either all at once or over a longer period of time (usually via a drip). Alternatively they may inject your heparin underneath your skin.

The amount injected all at once into a vein should not be greater than 15 mL.

You may need to have blood tests if you are receiving higher doses of heparin to check on the effects of your heparin treatment.

Heparin injection must not be given to premature or newborn babies.

You may require a lower dose if you have kidney or liver disease.

To prevent blood clots in leg veins (deep vein thrombosis) and blood clots in the lung (pulmonary embolism)

Adults
The usual dose of heparin injection in adults is 5,000 units injected under the skin 2 hours before your operation, followed by:
- 5,000 units injected under the skin every 8-12 hours, for 7-10 days or until you are fully able to move about.

Elderly
Lower doses may be used in the elderly. You may need to have blood tests if you are elderly, to check on the effects of your heparin treatment.

Children
No specific doses are recommended.

To treat blood clots in leg veins (deep vein thrombosis) and blood clots in the lung (pulmonary embolism)

Adults
The usual dose in adults is 5,000 units injected into a vein. This is followed by:
- 1,000-2,000 units/hour injected slowly into a vein or
- 5,000-10,000 units 4-hourly injected all at once into a vein.

Elderly
Lower doses may be used in the elderly.

Small adults and children
Small adults and children will be given 50 units/kg bodyweight injected into a vein followed by:
- 15-25 units/kg bodyweight/hour injected slowly into a vein or
- 100 units/kg bodyweight 4-hourly injected all at once into a vein.

To treat chest pains (unstable angina pectoris) and severe blood clots in the arteries (acute peripheral arterial occlusion)

Adults
The usual dose in adults is 5,000 units injected into a vein. This is followed by:
- 1,000-2,000 units/hour injected slowly into a vein or
- 5,000-10,000 units 4-hourly injected all at once into a vein.

Elderly
Lower doses maybe used in the elderly.

Small adults and children
Small adults and children will be given 50 units/kg body weight injected into a vein followed by:
- 15-25 units/kg bodyweight/hour injected slowly into a vein or
- 100 units/kg bodyweight 4-hourly injected all at once into a vein.

You will have blood tests every day to check the effects of your heparin.

To prevent a blood clot in the heart following a heart attack

Adults
The usual dose for adults is 12,500 units 12-hourly injected under the skin for at least 10 days.

Elderly
A lower dose may be needed.

During heart and lung surgery

Adults
Initially you will be given 300 units/kg body weight. This will be changed according to the results of your blood tests.

During kidney dialysis

Adults
Initially you will be given 1,000-5,000 units. This will be changed according to the results of your blood tests.

If you think you have been given too much Heparin Sodium ROVI 1,000 IU/mL
Your doctor will decide which dose is best for you.

Too much heparin can cause bleeding. Slight bleeding can be stopped by stopping your heparin treatment. However, if you have more severe bleeding you may need blood tests and an injection of a medicine called protamine sulphate.

If you think too much medicine has been given to you, contact your doctor or nurse.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

Important side effects to look out for (frequency not stated)**:**

Severe allergic reactions
Heparin can cause a rare severe allergic reaction with wheezing, difficulty breathing, a blue tinge to the lips, fever, chills, swelling of the eyes and lips and shock.

If you think you are having a severe allergic reaction you must stop receiving heparin and tell your doctor or nurse immediately.

Bleeding and bruising
Signs that you are bleeding more easily include:
- unusual bruising or purple spots on your skin,
- unusual bleeding from your gums,
- unusual nose bleeds,
- blood in your urine (which may cause this to go dark),
- black, tarry-looking stools,
- bleeding that will not stop from any operation site or other injury.

If you are concerned about unusual bleeding you must tell your doctor or nurse immediately as you may need to stop your heparin treatment.

Other side effects (frequency not stated) **include:**
- red lumps or red, itchy patches like eczema often develop 3-21 days after the start of heparin treatment, where injections have been given under the skin,
- irregularly shaped, red skin lesions with blisters,
- sloughing of skin may occur around the injection site,
- persistent erection of the penis,
- abnormal results for blood tests that report on how the liver is working,
- high level of blood fats after stopping heparin,
- high or low potassium levels. If affected you may feel tired and weak.

If heparin injection is given over many months, then the following may occur:
- hair loss,
- thinning of the bones (osteoporosis).

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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Heparin Sodium ROVI 1,000 IU/mL solution for injection

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

Your doctor or nurse will usually be responsible for storing and preparing injection before use and for checking that the vials have not passed their expiry date stated on the carton and the label. This medicine must not be used after the expiry date which is stated on the carton and the label. The expiry date refers to the last day of that month.

Heparin injection should not be given if it shows signs of deterioration such as discolouration.

This medicinal product does not require any special storage conditions.

After opening the vial, immediately administer the product.

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 Heparin Sodium ROVI 1,000 IU/mL solution for injection contains
- The active substance is heparin sodium.
- Each vial with 5 mL solution for injection contains 5,000 units of heparin sodium.
- The other ingredients are sodium chloride, benzyl alcohol (10 mg/mL), sodium hydroxide and water for injections.

What Heparin Sodium ROVI 1,000 IU/mL solution for injection looks like and contents of the pack
This product comes as a colourless, clear solution with no visible particles.
This product is available in packs of 10 vials of 5 mL solution for injection.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorization Holder
Laboratorios Farmacéuticos ROVI, S.A.
Julián Camarillo, 35,
28037 – Madrid. Spain

Manufacturer
ROVI PHARMA INDUSTRIAL SERVICES, S.A.
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The following information is intended for healthcare professionals only:

How to prepare and administer
By continuous intravenous infusion or by intermittent intravenous injection, or by subcutaneous injection. **The intravenous injection volume of heparin injection should not exceed 15 mL.** As the effects of heparin are short-lived, administration by intravenous infusion or subcutaneous injection is preferable to intermittent intravenous injections.

Recommended dose
Heparin sodium may be administered intravenously (in continuous infusion or bolus administration) or subcutaneously. **Do not administer by the intramuscular route, due to the risk of developing local haematoma.**

The heparin dose should be individualised and adjusted to clotting times.

The recommended dose varies according to the different indications, as follows:

Prophylaxis of deep vein thrombosis and pulmonary embolism
Adults:

2 hours pre-operatively:	5,000 units subcutaneously
followed by:	5,000 units subcutaneously every 8-12 hours, for 7-10 days or until the patient is fully ambulant

No laboratory monitoring should be necessary during low dose heparin prophylaxis. If monitoring is considered desirable, anti-Xa assays should be used as the activated partial thromboplastin time (APTT) is not significantly prolonged.

Elderly:
Dosage reduction and monitoring of APTT may be advisable.

Paediatric population:
No dosage recommendations.

Treatment of deep vein thrombosis and pulmonary embolism
Adults:

Loading dose:	5,000 units intravenously (10,000 units may be required in severe pulmonary embolism)
Maintenance:	1,000-2,000 units/hour by intravenous infusion, or 5,000-10,000 units 4-hourly by intravenous injection

Elderly:

Dosage reduction may be advisable.

Children and small adults:

Loading dose:	50 units/kg intravenously
Maintenance:	15-25 units/kg/hour by intravenous infusion, or 100 units/kg 4-hourly by intravenous injection

Treatment of unstable angina pectoris and acute peripheral arterial occlusion
Adults:

Loading dose:	5,000 units intravenously
Maintenance:	1,000-2,000 units/hour by intravenous infusion, or 5,000-10,000 units 4-hourly by intravenous injection

Elderly:
Dosage reduction may be advisable.

Children and small adults:

Loading dose:	50 units/kg intravenously
Maintenance:	15-25 units/kg/hour by intravenous infusion, or 100 units/kg 4-hourly by intravenous injection

Daily laboratory monitoring (ideally at the same time each day, starting 4-6 hours after initiation of treatment) is essential during full-dose heparin treatment, with adjustment of dosage to maintain an APTT value 1.5-2.5 x midpoint of normal range or control value.

Prophylaxis of mural thrombosis following myocardial infarction
Adults:
12,500 units 12-hourly subcutaneously for at least 10 days.

Elderly:
Dosage reduction may be advisable.

Prevention of thrombosis in extracorporeal circulation circuit during heart surgery and haemodialysis

Heart surgery: It is recommended to heparinise the patient with 300 units/kg, adjusted thereafter to maintain the activated clotting time (ACT) in the range 400-500 seconds.

Haemodialysis and haemofiltration:

Initially:	1,000-5,000 units
Maintenance:	1,000-2,000 units/hour, adjusted to maintain clotting time > 40 minutes

Heparin resistance
Patients with altered heparin responsiveness or heparin resistance may require disproportionately higher doses of heparin to achieve the desired effect.

Renal and hepatic impairment:
A lower dose may be necessary. It is recommended to adjust the dose in accordance with the weight and the required APTT levels.