

Patient Medication Guide

HEPASOLV[®]

(Heparin Sodium Injection)

Generic name: [Heparin Sodium]

Please read this leaflet before you start taking HEPASOLV[®] for injection and each time you are scheduled to receive HEPASOLV[®], since there may be new information. This leaflet does not take the place of careful discussions with your doctor about your medical condition or your treatment.

What is Acute Coronary Syndrome ?

Acute coronary syndrome (ACS) refers to any group of symptoms attributed to obstruction of the coronary arteries ie. Myocardial Infraction (MI), Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE), Venous Thrombosis.

What is an anti-coagulant ?

An anti-coagulant is a drug that helps prevent the clotting (coagulation) of blood. These drugs prevent new clots formation or an existing clot from enlarging. However they don't dissolve a blood clot. Anti-coagulants are also given to certain people at risk for forming blood clots, such as those with artificial heart valves or who have atrial fibrillation.

What is heparin sodium ?

Heparin sodium is an anticoagulant which prevents the blood from clotting. It is used to prevent and treat venous thrombosis, pulmonary embolism and other conditions of blood clotting.

How is HEPASOLV[®] (Heparin Sodium) administered ?

This medication is administered by a health care professional either as an injection or infused slowly into a vein over a period time. Blood tests will be done routinely to determine the appropriate dose.

When should one not use HEPASOLV[®] ?

Alert your doctor if you are allergic to heparin.

Alert your doctor if you have or ever had any of these conditions:

- bleeding disorders or problems with blood clotting
- stomach ulcers
- stroke or bleeding in the brain
- high blood pressure
- bacterial infection in your heart
- history of low platelet count during treatment with heparin

What should one take a note of while taking this medication ?

This medication is usually administered initially in the hospital where your condition can be monitored closely. Laboratory tests will be done periodically to be sure the drug is working properly and to monitor for possible side effects.

What side-effects could one experience on HEPASOLV[®] ?

This medication may cause irritation, pain, redness or swelling at the injection site. If these symptoms continue or become bothersome, inform your doctor. Notify your doctor if you develop signs of a possibly allergy: chills, fever, itchy skin, rash. Bleeding must be monitored for it may indicate the dose is too high. Notify your doctor if you experience any of the following while using this medication: easy bruising, nose bleed, dark and tarry stools, blood in urine, a bleeding episode. If you notice other effects not listed above, contact your doctor or pharmacist.

Are there any certain precautions before taking HEPASOLV[®] ?

Tell your doctor if you have: blood disorders, bleeding episodes, heart disease, ulcers, liver disease, kidney disease, any allergies. A preservative (benzyl alcohol) which may be found in this product or in the liquid used to mix this product (diluent) can infrequently cause serious problems (sometimes death) if given by injection to an infant during the first months of life (neonatal period). The risk is greater with lower birth weight infants and is greater with increased amounts of benzyl alcohol. Symptoms include sudden gasping, low blood pressure, or a very slow heartbeat. Report these symptoms to the doctor immediately should

they occur. If possible, a preservative-free product should be used when treating neonates. Elderly persons may be more sensitive to the effects of this medication. This medication should be used only if clearly needed during pregnancy. Discuss the risks and benefits with your doctor. It is not known if this medication appears in breast milk. Consult your doctor before breast-feeding.

Can one take HEPASOLV[®] with other medications ?

While you are using heparin sodium, it is important not to take any other medications (including over-the-counter medications, and especially those containing aspirin or other anti-inflammatory medicines) which are not prescribed or approved by your physician. Always read the product label.

Tell your doctor of any over-the-counter or prescription medication you take, especially of: blood thinners, aspirin, nitroglycerin, injectable antibiotics. Do not start or stop any medicine without doctor or pharmacist approval.

Are there any restrictions on the type of food one can take while on HEPASOLV[®] ?

Avoid alcohol.

What is the difference between heparin sodium (HEPASOLV[®]) and low-molecular-weight heparin[LMWH] (BIO-ENOX[®]) ?

LMWH and heparin are both used to prevent blood from clotting inside the body, but are used in different situations.

Heparin, sometimes called “standard heparin,” is available as a liquid solution injected directly into the blood (intravenous or “IV”) and only given to hospitalized patients, for instance, to prevent blood clots during surgery. Because patients vary widely in their response to heparin sodium, laboratory monitoring of anticoagulant activity is needed to adjust the dose of heparin and monitor its effect in the hospital. In addition, heparin has potential to cause a possibly deadly condition known as Heparin Induced Thrombocytopenia (HIT), where the body stops producing blood platelets. Thus, in the hospital, doctors can notice HIT right away and take action to reverse the condition. Doctors or other healthcare professionals must inject a patient with heparin. Patients cannot use heparin themselves.

LMWH, such as enoxaparin, is made from heparin. It is also available as a liquid injectable solution used to prevent blood clots, but it is used differently than heparin. LMWH produces a more predictable anticoagulant response so frequent monitoring is not needed to adjust the dose. LMWH is also designed to last much longer in the body, so it does not need to be injected intravenously. Instead, LMWH is injected under the skin. Additionally, LMWH has a lower incidence of HIT.