Patient Medication Guide

BIO-ENOX[®]

(Low Molecular Weight Heparin, Enoxaparin Sodium Injection)

Generic name: [Enoxaparin Sodium]

Please read this leaflet before you start taking $BIO\text{-}ENOX^{\circledR}$ for injection and each time you are scheduled to receive $BIO\text{-}ENOX^{\circledR}$, 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).

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 enoxaparin sodium therapy?

Enoxaparin sodium is an anticoagulant ("anti" means against and "coagulant" refers to clotting) that is used to help prevent the formation of blood clots in patients at risk. Enoxaparin, a low-molecular-weight heparin, is also used to treat patients with blood clots.

Why does one need this ${\sf BIO\text{-}ENOX}^{\circledR}$ (Enoxaparin Sodium) ?

 $\mathsf{BIO}\text{-}\mathsf{ENOX}^{\mathbb{R}}$ is a blood-thinning medicine that is given as an injection. $\mathsf{BIO}\text{-}\mathsf{ENOX}^{\mathbb{R}}$ reduces the formation of harmful blood clots in your body.

BIO-ENOX[®] is used to treat deep vein thrombosis (also known as DVT or blood clots in the leg veins) and pulmonary embolism (blood clots in the lungs). You may be at risk of getting

such blood clots after surgery or if you have been bed-bound most of the time.

 $\mathsf{BIO} ext{-}\mathsf{ENOX}^{\circledR}$ also prevents the formation of blood clots in the tubing during kidney dialysis.

BIO-ENOX[®] may also be used to prevent blood clots in certain types of heart disease.

When should one not use BIO-ENOX[®]?

Alert your doctor if you are allergic to heparin, other medicines similar to Enoxaparin.

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 or other medicines similar to Enoxaparin

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

Inform your doctor if you have any of these conditions or any other illnesses:

- kidney disease
- liver disease
- thinning of your bones (osteoporosis)
- low platelet count or suffer from cancer
- recent brain, spine or eye surgery
- an artificial heart valve
- certain eye problems due to high blood pressure or diabetes
- weigh less than 45 kg (women) or 57 kg (men)

Alert your doctor if you are pregnant or breastfeeding. Do not breastfeed while being treated with Enoxaparin. If you are going for an operation, including minor operations and dental work, inform your doctor or dentist that you are being treated with Enoxaparin.

Do not take part in activities in which you may fall or get injured such as contact sports. Take special care when shaving or handling sharp objects to avoid cutting yourself. Use a soft toothbrush when brushing your teeth to reduce the risk of gum bleeding.

What side-effects could one experience on BIO-ENOX $^{\circledR}$?

Enoxaparin may cause pain, bruising and irritation at the site of injection.

Enoxaparin may cause you to bleed more easily. Alert your doctor if you get any unusual bruising (large bruises or several bruises especially if they appear by themselves or if they cover a large area), or bleeding that takes a long time to stop (for example, too much bleeding when you floss or brush your teeth). Alert your doctor if you notice blood in your urine, bowel movements or if you get a nose bleed.

If you develop rashes, fever and itch, inform your doctor quickly. These could be signs of an allergic reaction. Enoxaparin may cause other side effects. Alert your doctor if you have unusual problems while being treated with Enoxaparin.

Can one take BIO-ENOX[®] with other medications?

While you are using enoxaparin, 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.

Aspirin and anti-inflammatory medicines will also increase the time it takes your blood to clot. These medications do not work the same way enoxaparin, but taking them with enoxaparin can increase your risk of bleeding.

Medicines that contain aspirin, salicylates (aspirin-like products), or non-steroidal antiinflammatory drugs should be avoided unless prescribed by your physician. These can include cold and allergy products, as well as pain relievers for headache, backache, muscle ache, arthritis, and menstrual cramps.

Are there are any restrictions on the type of food one can take while on Enoxaparin?

Avoid alcohol.

What is the difference between heparin sodium (HEPASOLV $^{(\!R\!)}$) and low-molecular-weight heparin[LMWH] (BIO-ENOX $^{(\!R\!)}$)?

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, LWMH has a lower incidence of HIT.