

Enoxaparin Sodium Injection USP

Low Molecular Weight Heparin

COMPOSITION:

Pack size:
20mg /0.2ml (2000 I.U. anti-Xa)
Contains 20mg of Enoxaparin sodium with Water for Injections q.s
40 mg /0.4 ml (4000 I.U. anti-Xa)
Contains 40mg of Enoxaparin sodium with Water for Injections q.s
60mg /0.6ml (6000 I.U. anti-Xa)
Contains 60mg of Enoxaparin sodium with Water for Injections q.s
80 mg /0.8ml (8000 I.U. anti-Xa)
Contains 80mg of Enoxaparin sodium with Water for injections q.s

PHARMACEUTICAL FORM:

Sterile, pyrogen-free, solution for injection contained in ready-to-use prefilled syringes.

PHARMACO-THERAPEUTIC CLASS

Antithrombotic/ low Molecular weight Heparin (B: blood, hematopoietic organs).

THERAPEUTIC INDICATIONS

Indicated for the prophylaxis of venous thromboembolic disease (prevention of blood clot formation in the veins), in particular when coupled with orthopaedic or general surgery.

Treatment of deep vein thrombosis (with or without pulmonary embolism)

Treatment of unstable angina non-Q-wave myocardial infarction, administered parallelly with aspirin.

Indicated as anticoagulant in extracorporeal circulation during hemodialysis.

METHOD OF ADMINISTRATION:

Administer by SUBCUTANEOUS ROUTE for prophylactic and curative treatment.

Administer by INTRAVENOUS ROUTE for hemodialysis.

DO NOT ADMINISTER BY THE

INTRAMUSCULAR ROUTE

The Enoxaparin sodium injection pre-filled Syringe supplied is ready to use disposable syringe.

Subcutaneous administration technique:

Do not expel the air bubble from the syringe before the injection to avoid loss of drug particularly in case of 0.60mg/0.6ml and 40mg/0.4ml Enoxaparin sodium injection.

The subcutaneous injection should preferably be made when the patient is lying down.

Administer the Enoxaparin sodium injection in The subcutaneous cellular tissue of the anterolateral posterolateral abdominal wall, alternately on the left and the right side.

Inject the whole length of the needle vertically into a skin fold gently held between the thumb and the index finger. Do not release the skin fold until the injection is completely given.

Do not rub the injection site after administration.

DOSEAGE

1.0mg of Enoxaparin sodium contains approximately 1001.U. of anti-Xa Activity. Prophylaxis of venous thrombosis:

Dosage of 20mg (0.2ml) is recommended once daily by a single subcutaneous injection in the case of a surgery with a moderate thrombotic risk and when patients do not present high thromboembolism risk.

Dosage of 40mg (0.4ml) is recommended once daily by a single subcutaneous injection in the case of a surgery with a high thrombotic risk (hip and knee surgery) and for in patients with a high risk of thromboembolism.

The first injection should be given 2 hours before the surgical procedure. In orthopaedic surgery, the first injection is to be given 12 hours pre-operatively. A higher Count level): your physician should be informed immediately

- Rare incidences of severe skin rash at Injection sites: consult your physician.

-Risk of osteoporosis (bone demineralization leading to bone fragility) if treatment is administered over several months.

-Increased blood level of certain enzymes (transaminases)

Cases of neuraxial hematomas with the concurrent use of enoxaparin and spinal/epidural anesthesia or spinal puncture which may have resulted in varying degrees of neurologic injuries including long term or permanent paralysis have been reported (see section: Special warnings). Do not hesitate to ask your physician or pharmacist for advice and to report any undesirable effect not mentioned in this leaflet.

ACTION TO BE TAKEN IN CASE OF OVERDOSAGE:

Accidental over dosage after subcutaneous injection of massive doses of enoxaparin could lead to bleeding complications. Neutralization can be obtained by slow intravenous injection of protamine. (1 mg protamine can be used to neutralize the anticoagulant effect of about 1 mg enoxaparin).

in case of over dosage or accidental Intoxication you must notify to a physician

PHARMACOLOGICAL PROPERTIES:

Pharmacodynamic properties
Enoxaparin is a low molecular weight heparin With a high anti-Xa activity (1001.U/mg), and With a low anti-II a or anti thrombin activity (281.U/mg). At doses required for the various indications, enoxaparin does not increase bleeding time. At preventive doses, enoxaparin

causes no notable modification of ap TT. It neither influences platelet aggregation nor binding of fibrinogen to platelets.

Pharmacokinetic Properties

The pharmacokinetic parameters have been Studies in terms of the time course of plasma anti-Xa activity.

Bioavailability: After subcutaneous injection, Enoxaparin is rapidly and completely absorbed. The bio availability of enoxaparin is Close to 95%

Distribution: After subcutaneous injection, the Maximum plasma activity is obtained 3 hours after the administration. The anti-Xa activity is located in the vascular space.

Biotransformation

Enoxaparin is primarily metabolized in the liver.

Elimination

The elimination appears with half-life of approximately 4 hours dose to about 7 hours after repeated dosing.

Excretion

Enoxaparin is eliminated in the urine. Elimination is slightly reduced in elderly.

LIST OF EXCIPIENTS: water for injections

Shelf-life : 24 months from the date of manufacturing.

Storage precautions

Store below 25°C. Do not freeze. Keep all medicines out of reach of children.

Delivered under medical prescription only.

Presentation: 1 Pre - filled syringe.

Manufactured in India:

