Pack Insert
Date : 04-08-2018
Date : 06-08-2018*
Date : 23-11-2018**
Date : 27-11-2018***
(ZEN Pharma (P) Ltd.) (LL)
(Revised)
Version-4

SIDE EFFECTS & ADVERSE REACTIONS:
Hemorrhage:
The incidence of major hemorrhagic complications during Lonopin™ treatment has been low.

Thrombocytopenia:
[See WARNINGS and PRECAUTIONS]

Elevations of Serum Aminotransferases:
Asymptomatic increases in aspartate (AST [SGOT]) and alanine (ALT [SGPT]) aminotransferase levels greater than three times the upper limit of normal of the labgatory reference range have been reported in up to 6.1% and 5.9% of patients, respectively, during treatment with Lonopin™. Similar significant increases in aminotransferase levels have also been observed in patients and healthy volunteers treated with heparin and other low molecular weight heparins. Such elevations are fully reversible and are rarely associated with increases in bilirubin.

Since aminotransferase determinations are important in the differential diagnosis of myocardial infarction, liver disease, and pulmonary emboli, elevations that might be caused by drugs like Lonopin™ should be interpreted with caution.

Local Reactions:
Mild local irritation, pain, hematoma, ecchymosis, and erythema may follow SC injection of Lonopin™.

DRUG INTERACTIONS:
Unless really needed, agents which may enhance the risk of hemorrhage should be discontinued prior to initiation of Lonopin™ therapy. These agents include medications such as: anticoagulants, platelet inhibitors including acetylsalicylic acid, salicylates, NSAIDs (including ketorolac tromethamine), dipyridamole, or sulfinpyrazone. If co-administration is essential, conduct close clinical and laboratory monitoring [see WARNINGS and PRECAUTIONS].

Incompatibility:
Do not mix Lonopin™ with other injections or infusions. (See PRECAUTIONS).

Laboratory Test Interactions:
Transaminase determinations:
Drug causes asymptomatic elevations in AST and ALT.

PATIENT INFORMATION:
INSTRUCTIONS FOR PATIENTS - SELF ADMINISTRATION:

Remove the needle shield by pulling it straight off the syringe.
If adjusting the dose is required, the dose adjustment must be done prior to injecting the prescribed dose to the patient.
(see Figure A).

Figure A

Cleanse the injection site with a new alcohol swab.
Hold the skin the way you were instructed.
Slide the needle quickly all the way through the skin, into the subcutaneous tissue at a 90° angle.
(see Figure B).

Figure B

Remove the syringe from the injection site.
Withdraw the needle at the same angle it was inserted (90°).
Dab an alcohol swab on the skin.
(see Figure C).

Figure C

Immediately dispose of the syringe in the nearest sharps container or apropriate disposal unit after putting the cap back on the needle
(see Figure D).

Figure D

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES: Enoxaparin has no effect on the ability to drive and operate machines.

STORAGE: Store below 25°C. Do not freeze. Keep out of reach of children.

PRESENTATION:
Lonopin™ **20mg:** Each carton comprises 1 Pre-filled Syringe containing 20mg (2000 anti-Xa I.U. / 0.2mL) Enoxaparin sodium in a blister pack along with a pack insert.
Lonopin™ **40mg:** Each carton comprises 1 Pre-filled Syringe containing 40mg (4000 anti-Xa I.U. / 0.4mL) Enoxaparin sodium in a blister pack along with a pack insert.
Lonopin™ **60mg:** Each carton comprises 1 Pre-filled Syringe containing 60mg (6000 anti-Xa I.U. / 0.6mL) Enoxaparin sodium in a blister pack along with a pack insert.

SHELF LIFE: 24 Months.

REFERENCES:

a) Trissel LA, ed. Handbook on Injectable Drugs. 14th Edition. Bethesda, MD : American Society of Health-System Pharmacists; 2007
b) Sweetman SC, ed. Martindale : The Complete Drug Reference. 34th Edition. London, England : The Pharmaceutical Press; 2005.
c) McEvoy GK, ed. AHFS Drug Information 2005. Bethesda, MD : American Society of Health-System Pharmacists; 2005.

To report Suspected Adverse Reactions, contact Bharat Serums and Vaccines at pv@bharatserums.com or visit the website www.bharatserums.com/adverse.html

Manufactured in India by:
BHARAT SERUMS AND VACCINES LIMITED
U-5 Kala Darshan, B/H, Rahul Appartment, Satellite, Ahmedabad - 380 015,
Taluka: Jodhpur, District: Ahmedabad-II
At.: 75/1, G.I.D.C., Vapi - 396 195, Gujarat.
Regd. Off.: 17th Floor, Hoechst House, Nariman Point, Mumbai - 400 021.

IN045TDZP2LL

TM = Trade Mark

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

Rx

Enoxaparin Injection IP 20mg / 40mg / 60mg

लोनोपीन
Lonopin™

20mg/0.2mL, 40mg/0.4mL, 60mg/0.6mL

Low Molecular Weight Heparin

For Subcutaneous or Intravascular Use

COMPOSITION:
Each Pre-filled syringe contains:
Enoxaparin Sodium IP.....20mg / 40mg / 60mg
Water for Injections IP.....q.s. to 0.2mL / 0.4mL / 0.6mL

Enoxaparin Sodium starting material is porcine derived.

DESCRIPTION:
Lonopin™ is a sterile aqueous solution containing Enoxaparin Sodium, a Low Molecular Weight Heparin (LMWH), in single dose ready-to-use prefilled syringes intended for subcutaneous or intravascular use.

Enoxaparin Sodium is obtained by alkaline depolymerisation of heparin benzyl ester derived from porcine intestinal mucosa. The drug substance is the sodium salt. The mean molecular weight is about 4500 daltons.

CLINICAL PHARMACOLOGY:
Mechanism of Action:
Enoxaparin is a Low Molecular Weight Heparin which has higher ratio of antithrombotic activity to anticoagulant activity than unfractionated heparin. Enoxaparin binds to anti-thrombin III leading to coagulation factor IIa and Xa.

Pharmacodynamics:
In humans, enoxaparin given at a dose of 1.5 mg/kg subcutaneously (SC) is characterized by a higher ratio of anti-Factor Xa to anti-Factor IIa activity compared to the ratios observed for heparin. At preventive doses, enoxaparin sodium causes no notable modification of activated partial thromboplastin time (aPTT). It neither influences platelet aggregation nor binding of fibrinogen to platelets. Enoxaparin Sodium is primarily metabolized in the liver.

Pharmacokinetics:
Absorption: Subcutaneously administered enoxaparin shows almost 100% bioavailability.
Maximum (Peak) anti-Factor Xa and anti-thrombin (anti-Factor IIa) activities occur 3 to 5 hours after subcutaneous injection of enoxaparin.

Distribution: The volume of distribution of anti-Factor Xa activity is about 4.3 L.

Elimination: Apparent clearance is approximately 15 mL/min for SC dosing. For IV dosing, the total body clearance is 26 mL/min.

The $t_{1/2}$ is 4.5 hr (based on anti-factor Xa activity).

Significant anti-Factor Xa activity persists in plasma for about 12 hours following a 40mg SC once a day dose.

Metabolism: Enoxaparin Sodium is primarily metabolized in the liver by desulfation and/or depolymerization to lower molecular weight species with much reduced biological potency. Renal clearance of active fragments represents about 10% of the administered dose and total renal excretion of active and non-active fragments is 40% of the dose.

(Patients with Severe Renal Impairment (creatinine clearance < 30mL/minute) Refer to Table 1).

INDICATIONS, DOSAGE AND ADMINISTRATION:
All patients should be evaluated for a bleeding disorder before administration of Lonopin™, unless the medication is needed urgently. Since coagulation parameters are unsuitable for monitoring Lonopin™ activity, routine monitoring of coagulation parameters is not required [see WARNINGS and PRECAUTIONS].

For Subcutaneous use: Lonopin™ should not be mixed with other injections or infusions.

For Intravenous use (i.e. for treatment of acute STEMI): Lonopin™ 60mg can be used. Enoxaparin sodium may be safely administered with normal saline solution (0.9%) or 5% Dextrose Injection in water.

Lonopin™ is not intended for intramuscular administration.

Indication and Dosage:
Abdominal Surgery:
In patients undergoing abdominal surgery who are at risk for thromboembolic complications, the recommended dose of Lonopin™ is 40 mg once a day administered by SC injection with the initial dose given 2 hours prior to surgery. The usual duration of administration is 7 to 10 days.

Hip or Knee Replacement Surgery:
In patients undergoing hip or knee replacement surgery, the recommended dose of Lonopin™ is 30 mg every 12 hours administered by SC injection. Provided that hemostasis has been established, the initial dose should be given 12 to 24 hours after surgery. For hip replacement surgery, a dose of 40 mg once a day SC, given initially 12 (±3) hours prior to surgery, may be considered. Following the initial phase of thromboprophylaxis in hip replacement surgery patients, it is recommended that continued prophylaxis with Lonopin™ 40 mg once a day is administered by SC injection for 3 weeks. The usual duration of administration is 7 to 10 days.

Medical Patients During Acute Illness:
In medical patients at risk for thromboembolic complications due to severely restricted mobility during acute illness, the recommended dose of Lonopin™ is 40 mg once a day administered by SC injection. The usual duration of administration is 6 to 11 days.

Treatment of Deep Vein Thrombosis (DVT) with or without Pulmonary Embolism:
In **outpatient treatment**, patients with acute DVT without pulmonary embolism who can be treated at home, the recommended dose of Lonopin™ is 1 mg/kg every 12 hours administered SC. In **inpatient (hospital) treatment**, patients with acute DVT with pulmonary embolism or patients with acute DVT without pulmonary embolism (who are not candidates for outpatient treatment), the recommended dose of Lonopin™ is 1 mg/kg every 12 hours administered SC or 1.5 mg/kg once a day administered SC at the same time every day. In both outpatient and inpatient (hospital) treatments, warfarin sodium therapy should be initiated when appropriate (usually within 72 hours of Lonopin™). Lonopin™ should be continued for a minimum of 5 days and until a therapeutic oral anticoagulant effect has been achieved (International Normalization Ratio 2.0 to 3.0). The average duration of administration is 7 days.

Unstable Angina and Non-Q-Wave Myocardial Infarction:
In patients with unstable angina or non-Q-wave myocardial infarction, the recommended dose of Lonopin™ is 1 mg/kg administered SC every 12 hours in conjunction with oral aspirin therapy (100 to 325 mg once daily). Treatment with Lonopin™ should be prescribed for a minimum of 2 days and continued until clinical stabilization. The usual duration of treatment is 2 to 8 days. In geriatric patients, no dosage adjustment is necessary in preventive therapy. In curative therapy, measurement of anti-Xa activity is recommended. [See WARNINGS and PRECAUTIONS].

Treatment of Acute ST-Segment Elevation Myocardial Infarction:
In patients with acute ST-segment elevation myocardial infarction, the recommended dose of Lonopin™ is a **single IV bolus of 30 mg** plus a 1 mg/kg SC dose followed by 1 mg/kg administered SC every 12 hours (maximum 100 mg for the first two doses only, followed by 1 mg/kg dosing for the remaining doses). Dosage adjustments are recommended in patients ≥75 years of age [see DOSAGE AND ADMINISTRATION]. All patients should receive aspirin as soon as they identified as having STEMI and maintained with 75 to 325mg once daily unless contraindicated.

Size : L x H = 160 x 160 mm

Pantone Process Black C **50% Pantone Process Black C**

Paper : 60 gsm, Maplitho White
Outline & Cutting marks not to print
Artwork Code No. : IN045TDZP2LL
Back to Back Printing
1 Vertical & 3 Horizontal Folds

Pack Insert
Date : 04-08-2018
Date : 06-08-2018*
Date : 23-11-2018**
Date : 27-11-2018***
(ZEN Pharma (P) Ltd.) (LL)
(Revised)
Version-4

When administered in conjunction with a thrombolytic (fibrin-specific or non-fibrin specific), Lonopin™ should be given between 15 minutes before and 30 minutes after the start of fibrinolytic therapy. An optimal duration of treatment is not known, but it is likely to be longer than 8 days.

For patients managed with Percutaneous Coronary Intervention (PCI): If the last Lonopin™ SC administration was given less than 8 hours before balloon inflation, no additional dosing is needed. If the last Lonopin™ SC administration was given more than 8 hours before balloon inflation, an IV bolus of 0.3 mg/kg of Lonopin™ should be administered [see WARNINGS and PRECAUTIONS].

Prevention of extracorporeal thrombus formation in haemodialysis:
FOR INJECTION BY THE INTRAVASCULAR ROUTE (in the arterial line of the dialysis circuit):
The recommended dose is 1mg/kg. Enoxaparin should be introduced in the arterial line of the circuit at the beginning of the dialysis session. The effect of this dose is usually sufficient for a 4 hour session. However, if fibrin rings are found, a further dose of 0.5 to 1mg/kg may be given. For patients at a high risk of haemorrhage the dose should be reduced to 0.5mg/kg for double vascular access or 0.75mg/kg for single vascular access.

Renal Impairment:
Although no dose adjustment is recommended in patients with moderate (creatinine clearance 30-50mL/min) and mild (creatinine clearance 50-80mL/min) renal impairment, all such patients should be observed carefully for signs and symptoms of bleeding.

The recommended prophylaxis and treatment dosage regimens for patients with severe renal impairment (creatinine clearance < 30mL/min) are described in Table 1.

Table 1
Dosage Regimens for **Patients with Severe Renal Impairment**
(creatinine clearance < 30mL/minute)

INDICATIONS	DOSAGE REGIMEN
Prophylaxis in abdominal surgery	30 mg administered SC once daily
Prophylaxis in hip or knee replacement surgery	30 mg administered SC once daily
Prophylaxis in medical patients during acute illness	30 mg administered SC once daily
Inpatient treatment of acute DVT with or without pulmonary embolism, when administered in conjunction with warfarin sodium	1 mg/kg administered SC once daily
Outpatient treatment of acute DVT without pulmonary embolism, when administered in conjunction with warfarin sodium	1 mg/kg administered SC once daily
Prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction, when concurrently administered with aspirin	1 mg/kg administered SC once daily
Treatment of acute ST-segment elevation myocardial infarction in patients <75 year of age, when administered in conjunction with aspirin	30 mg single IV bolus plus a 1mg/kg SC dose followed by 1mg/kg administered SC once daily.
Treatment of acute ST-segment elevation myocardial infarction in geriatric patients ≥75 years of age, when administered in conjunction with aspirin	1mg/kg administered SC once daily (no initial bolus)

Geriatric Patients with Acute ST-Segment Elevation Myocardial Infarction:
For treatment of acute ST-segment elevation myocardial infarction in geriatric patients ≥75 years of age, do not use an initial IV bolus. Initiate dosing with 0.75mg/kg every 12 hours (maximum 75mg for the first two doses only, followed by 0.75mg/kg SC every 12 hours (maximum 75mg for the first two doses only, followed by 0.75mg/kg dosing for the remaining doses).

No dose adjustment is necessary for other indications in geriatric patients unless kidney function is impaired [see DOSAGE AND ADMINISTRATION].

Administration:
Lonopin™ is a clear, colourless to pale yellow sterile solution, and as with other parenteral drug products, should be inspected visually for particulate matter / discolouration prior to administration.

Lonopin™ must not be administered by intramuscular injection.

Lonopin™ is intended for use under the guidance of a physician.

For subcutaneous administration, patients may self-inject only if their physicians determine that it is appropriate and with medical follow-up, as necessary. Proper training in subcutaneous injection technique (with or without the assistance of an injection device) should be provided.

Subcutaneous Injection Technique: Patients should be lying down and Lonopin™ administered by deep SC injection. Administration should be alternated between the left and right anterolateral and left and right posterolateral abdominal wall. The whole length of the needle should be introduced into a skin fold held between the thumb and forefinger; the skin fold should be held throughout the injection. To minimize bruising, do not rub the injection site after completion of the injection.

Intravenous (Bolus) Injection Technique: For intravenous injection, Lonopin™ 60mg should be administered through an intravenous line. Lonopin™ should not be mixed or co-administered with other medications. To avoid the possible mixture of Lonopin™ with other drugs, the intravenous access chosen should be flushed with a sufficient amount of saline or dextrose solution prior to and following the intravenous bolus administration of Lonopin™ to clear the port of drug. Lonopin™ 60mg may be safely administered with normal saline solution (0.9%) or 5% dextrose in water.

OVERDOSE:
Accidental overdosage following administration of enoxaparin sodium may lead to hemorrhagic complications. Injected Lonopin™ may be largely neutralized by the slow IV injection of protamine sulfate (1% solution). The dose of protamine sulfate should be equal to the dose of Lonopin™ injected : 1mg protamine sulfate should be administered to neutralize 1 mg Lonopin™, if enoxaparin sodium was administered in the previous 8 hours. An infusion of 0.5mg protamine per 1mg of enoxaparin sodium may be administered if enoxaparin sodium was administered greater than 8 hours previous to the protamine administration, or if it has been determined that a second dose of protamine is required. The second infusion of 0.5mg protamine sulfate per 1mg of Lonopin™ may be administered if the aPTT measured 2 to 4 hours after the first infusion remains prolonged.

If at least 12 hours have elapsed since the last enoxaparin sodium injection, protamine administration may not be required; however, even with higher doses of protamine, the aPTT may remain more prolonged than following administration of heparin. In all cases, the anti-Factor Xa activity is never completely neutralized (maximum about 60%). Particular care should be taken to avoid overdosage with protamine sulfate. Administration of protamine sulfate can cause severe hypotensive and anaphylactoid reactions. Because fatal reactions, often resembling anaphylaxis, have been reported with protamine sulfate, it should be given only when resuscitation techniques and treatment of anaphylactic shock are readily available. For additional information consult the labeling of protamine sulfate injection products.

CONTRAINDICATIONS:
This medicine **SHOULD NOT BE USED** in the following situations:
- Active major bleeding: Active GI ulcer or organic lesion likely to bleed.
- Thrombocytopenia associated with a positive in vitro test for anti-platelet antibody in the presence of enoxaparin sodium.
- Known hypersensitivity to enoxaparin sodium (e.g., pruritus, urticaria, anaphylactoid reactions) [see ADVERSE REACTIONS].
- Known hypersensitivity to heparin or pork products. Acute infectious endocarditis (inflammation of the inner lining of the heart) except when affecting a mechanical valve replacement.

PRECAUTIONS:
Increased Risk of Hemorrhage:
Cases of epidural or spinal hematomas have been reported with the associated use of enoxaparin sodium and spinal/epidural anesthesia or spinal puncture resulting in long-term or permanent paralysis. The risk of these events is higher with the use of post-operative indwelling epidural catheters or by the concomitant use of additional drugs affecting hemostasis such as NSAIDs [see WARNINGS, ADVERSE REACTIONS and DRUG INTERACTIONS].

Enoxaparin sodium should be used with extreme caution in conditions with increased risk of hemorrhage, such as bacterial endocarditis, congenital or acquired bleeding disorders, active ulcerative and angiodysplastic gastrointestinal disease, hemorrhagic stroke, or shortly after brain, spinal, or ophthalmologic surgery, or in patients treated concomitantly with platelet inhibitors. Major hemorrhages including retroperitoneal and intracranial bleeding have been reported.

Some of these cases have been fatal.

Bleeding can occur at any site during therapy with enoxaparin sodium. An unexplained fall in hematocrit or blood pressure should lead to a search for a bleeding site.

Percutaneous coronary revascularization procedures:
To minimize the risk of bleeding following the vascular instrumentation during the treatment of unstable angina, non-Q-wave myocardial infarction and acute ST-segment elevation myocardial infarction, adhere precisely to the intervals recommended between Lonopin™ doses. It is important to achieve hemostasis at the puncture site after PCI. If a manual compression method is used, sheath should be removed 6 hours after the last IV/SC Lonopin™. If the treatment with enoxaparin sodium is to be continued, the next scheduled dose should be given no sooner than 6 to 8 hours after sheath removal. The site of the procedure should be observed for signs of bleeding or hematoma formation [see DOSAGE AND ADMINISTRATION].

Use of Lonopin™ with Concomitant Medical Conditions:
Lonopin™ should be used with care in patients with a bleeding diathesis, uncontrolled arterial hypertension or a history of recent gastrointestinal ulceration, diabetic retinopathy and hemorrhage.

History of Heparin-induced Thrombocytopenia:
Lonopin™ should be used with extreme caution in patients with a history of heparin-induced thrombocytopenia.

Thrombocytopenia:
Thrombocytopenia can occur with the administration of enoxaparin sodium.
Thrombocytopenia of any degree should be monitored closely. If the platelet count falls below 100,000/mm^2, Lonopin™ should be discontinued. [see WARNINGS and PRECAUTIONS].

Pregnant Women with Mechanical Prosthetic Heart Valves:
Women with mechanical prosthetic heart valves may be at higher risk for thromboembolism during pregnancy, and, when pregnant, have a higher rate of fetal loss from stillbirth, spontaneous abortion and premature delivery. Therefore, frequent monitoring of peak and through anti-Factor Xa levels, and adjusting of dosage may be needed.

Laboratory Tests:
Periodic complete blood counts, including platelet count, and stool occult blood tests are recommended during the course of treatment with Lonopin™. When administered at recommended prophylaxis doses, routine coagulation tests such as Prothrombin Time (PT) and Activated Partial Thromboplastin Time (aPTT) are relatively insensitive measures of Lonopin™ activity and, therefore, unsuitable for monitoring. Anti-Factor Xa may be used to monitor the anticoagulant effect of Lonopin™ in patients with significant renal impairment. If during Lonopin™ therapy abnormal coagulation parameters or bleeding should occur, anti-Factor Xa levels may be used to monitor the anticoagulant effects of Lonopin™.

USE IN SPECIFIC POPULATIONS:
Pregnancy:
Pregnancy Category B:
All pregnancies have a background risk of birth defect, loss, or other adverse outcome regardless of drug exposure.

Pregnancy alone confers an increased risk for thromboembolism that is even higher for women with thromboembolic disease and certain high risk pregnancy conditions. While not adequately studied, pregnant women with mechanical prosthetic heart valves may be at even higher risk for thrombosis. Pregnant women with thromboembolic disease, including those with mechanical prosthetic heart valves and those with inherited or acquired thrombophilias, have an increased risk of other maternal complications and fetal loss regardless of the type of anticoagulant used.

All patients receiving anticoagulants, including pregnant women, are at risk for bleeding. Pregnant women receiving enoxaparin should be carefully monitored for evidence of bleeding or excessive anticoagulation. Consideration for use of a shorter acting anticoagulant should be specifically addressed as delivery approaches. Hemorrhage can occur at any site and may lead to death of mother and/or fetus. Pregnant women should be apprised of the potential hazard to the fetus and the mother if enoxaparin is administered during pregnancy.

Fetal Risk Summary:
Enoxaparin sodium does not cross the placenta, and is not expected to result in fetal exposure to the drug.

Nursing Mothers:
It is not known whether enoxaparin sodium is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from enoxaparin sodium, a decision should be made whether to discontinue nursing or discontinue enoxaparin sodium, taking into account the importance of enoxaparin sodium to the mother and the known benefits of nursing.

Pediatric Use:
Safety and effectiveness of enoxaparin sodium in pediatric patients have not been established.

Geriatric Use:
The efficacy of enoxaparin sodium in the geriatric (≥65 years) was similar to that seen in younger patients (<65 years). The risk of enoxaparin sodium associated bleeding increased with age. Serious adverse events increased with age for patients receiving enoxaparin sodium. There is no additional differences in the safety of enoxaparin sodium between geriatric and younger patients. Careful attention to dosing intervals and concomitant medications (especially antiplatelet medications) is advised. Enoxaparin sodium should be used with care in geriatric patients who may show delayed elimination of enoxaparin sodium. Monitoring of geriatric patients with low body weight (<45 kg) and those predisposed to decreased renal function should be considered.

In treatment of Acute ST-segment elevation myocardial infarction, the incidence of bleeding complications was higher in ≥ 65 years of age as compared to younger patients (<65 years).

Hepatic Impairment:
Caution should be exercised when administering enoxaparin sodium to patients with hepatic impairment.

Renal impairment:
Treatment with enoxaparin has been associated with development of hyperkalemia in patients with renal impairment.

Low-Weight Patients:
An increase in exposure of enoxaparin sodium with prophylactic dosages (non-weight adjusted) has been observed in low-weight women (<45 kg) and low-weight men (<57 kg). All such patients should be observed carefully for signs and symptoms of bleeding.

Obese Patients:
Obese patients are at higher risk for thromboembolism. The safety and efficacy of prophylactic doses of Enoxaparin Sodium Injection in obese patients (BMI >30kg/m2) has not been fully determined and there is no consensus for dose adjustment. These patients should be observed carefully for signs and symptoms of thromboembolism.

Interchangeability with Other Heparins:
Lonopin™ cannot be used interchangeably (unit for unit) with heparin or other low molecular weight heparins as they differ in manufacturing process, molecular weight distribution, anti-Xa and anti-IIa activities, units, and dosage. Each of these medicines has its own instructions for use.

WARNINGS: SPINAL / EPIDURAL HEMATOMAS
When neuraxial anesthesia (epidural/spinal anesthesia) or spinal puncture is employed, patients anticoagulated or scheduled to be anticoagulated with low molecular weight heparins or heparinoids for prevention of thromboembolic complications are at risk of developing an epiduralor spinal hematoma which can result in long-term or permanent paralysis.
The risk of these events is increased by the use of indwelling epidural catheters for administration of analgesia or by the concomitant use of drugs affecting hemostasis such as non steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, or other anticoagulants. The risk also appears to be increased by traumatic or repeated epidural or spinal puncture. A history of spinal deformity or spinal surgery increases the risk of developing epidural or spinal hematomas.
Monitor patients for signs and symptoms of neurological impairment. If neurologic compromise is noted, urgent treatment is necessary.
Consider the potential benefit versus risk before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis [see WARNINGS and PRECAUTIONS and DRUG INTERACTIONS].

Size : L x H = 160 x 160 mm

Pantone Process Black C **50% Pantone Process Black C**

Paper : 60 gsm, Maplitho White
Outline & Cutting marks not to print
Artwork Code No. : IN045TDZP2LL
Back to Back Printing
1 Vertical & 3 Horizontal Folds