PACKAGE INSERT Enoxaparin Sodium Injection IP 40 mg/0.4 ml

WINOXARIN 40

Each Pre-Filled Syringe Contains: Enoxanarin Sodium IP 40 mg (4000 anti-factor Xa-units) Water for Injection



CLINICAL PHARMACOLOGY

rmacotherapeutic group: Antithrombotic agent, heparin group, ATC code: B01A B05

Final Industriation (Industrial Industrial I humans. Beyond is an XVII approximately zero ingly wine is about 50 or 1 and 5 effect of enoxaparin sodium. When used as prophylactic treatment, enoxaparin sodium does not significantly affect the aPTT. When used as curative treatment, aPTT can be prolonged by 1.5-2.2 times the control time at peak activity.

General characteristics

The pharmacokinetic parameters of enoxaparin sodium have been studied primarily in terms of the time course of plasma anti-Xa activity and also by anti-Ila activity, at the recommended dosage ranges after single and repeated SC administration and after single IV administration. The quantitative determination of anti-Xa and anti-Ila pharmacokinetic activities was conducted by validated amidolytic methods.

Absorption

The absorption social maintenance 30 + 50 mil, min) and mind (creatinine clearance 50 + 80 mil, min) and mind (creatinine c The mean maximum plasms anti-Na activity level is observed 3 to 5 hours after SC injection and achieves approximately 0.2, 0.4, 1.0 and 1.3 anti-Na Ulmr. (following single SC administration of 2,000 UL, 4,000 UL, 100 UN, 400 mill (blue), 20 mill, 40 mill, mill, mill, 20 mill, 40 mill, mill, 20 mill, 40 mill, mill, 20 mill, 40 twice daily and 150 IU/kg (1.5 mg/kg) once daily, respectively

Distribution
The volume of distribution of enoxaparin sodium anti-Xa activity is about 4.3 litres and is close to the blood volume.

paging sodium is primarily metabolized in the liver by desulfation and/or depolymerization to lower molecular weight species with much reduced biological potency

Special populations

an increase in the severity of hepatic impairment (assessed by Child-Pugh categories). This decrease was mainly attributed to a decrease in ATIII level secondary to a reduced synthesis of ATIII in patients with hepatic impairment.

A linear relationship between anti-Xa plasma clearance and creatinine clearance at steadystate has been observed, which indicates decreased clearance of enoxaparin sodium in patients with reduced renaf function. Anti-Xa exposure represented by AUC, at shady-state, is marginally increased in mild (creatinine clearance 50-80 mL/min) and moderate (creatinine clearance 30-50 mL/min) renal impairment after repeated SC 4,000 IL (4mg) once daily obes, in patients with severe renal impairment (creatinine clearance 430-80 mL/min) renal impairment after repeated SC 4,000 IL (4mg) once daily obes. In patients with severe renal impairment (creatinine clearance 430 mL/min), the AUC is statesy state is significantly increased on averaged SC 3,000 IL (4mg) once daily obes.

Enoxaparin sodium pharmacokinetics appeared similar than control population, after a single 25 IU, 50 IU or 100 IU/kg (0.25, 0.50 or 1.0 mg/kg) IV dose however, AUC was twofold higher than control

After repeated SC 150 IU/kg (1.5 mg/kg) once daily dosing, mean AUC of anti-Xa activity is marginally higher at steady state in obese healthy volunteers (BMI 30-48 kg/m²) compared to non-obese control subjects, while maximum plasma anti-Xa activity level is not increased. There is a lower weight-adjusted clearance in phese subjects with SC dosing. When non-weight adjusted dosing was administered, it was found after a single-SC 4,000 III (40 mg).

dose, that anti-Xa exposure is 52% higher in low-weight women (<45 kg) and 27% higher in low-weight men (<57 kg) when compared to normal weight control Pharmacokinetic interactions

No pharmacokinetic interactions were observed between enoxaparin sodium and thrombolytics when administered concomitantly.

· Prophylaxis of venous thromboembolic disease in moderate and high risk surgical patients, in particular those undergoing orthopaedic or general surgery including cancer

- Prophylaxis of venous thromboembolic disease in medical patients with an acute illness (such as acute heart failure, respiratory insufficiency, severe infections or rheumatic

 | This administered through the arterial line of a dialysis circuit for the prevention of thrombus formation in the extra corporeal circulation during haemodialysis. diseases) and reduced mobility at increased risk of venous thromboembolism.
- Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery.

Texasongy given a true interpret in a control costs and window the tasks.

Prophylyvaris of venous thromboembolic disease in moderate and high risk surgical patients individual thromboembolic risk for patients can be estimated using validated risk. Administration in spinal/ejodural anaesthesia of lumbar puncture stratification model. In patients at moderate risk of thromboembolism, the recommended dose of enovaparin sodium is 2,000 IU (20 mg) once daily by subcutaneous (SC). Should the physician decide to administer articocaquidation in the context of epidural or spinal anaesthesia/analgesia or lumbar puncture, careful neurological monitoring is

injection. Properative initiation (2) hours before surgery of encaparin sodium 2,000 IU (20 mg) was proven effective any 9 sourcements of the proposal properative initiation (2) hours before surgery of encaparin sodium 2,000 IU (20 mg) was proven effective any 9 sourcements of the proposal properative initiation (2) hours before surgery of encaparin sodium 2,000 IU (20 mg) was proven effective and staff in moderate risk surgery.

In moderate risk patients, encaparin sodium treatment should be maintained for a minimal period of 7-10 days whatever the recovery status (e.g. mobility). Prophylaxis source of the patient not longer that a significantly reduced mobility. In patients a thip risk of thrombombolism, the recommended due to the risk of neuraxialishmentamoms.

-// doess used for prophylaxis

-// doess used for prop (e.g. high risk patient waiting for a differed orthopaedic surgery), the last injection should be administered no later than 12 hours prior to surgery and resumed 12 hours after

surgery. For natients who undergo major orthogaedic surgery an extended thromboprophylaxis up to 5 weeks is recommended. For natients with a high venous thromboembolism surger; or upwares were quality of the property of the propert dup's winsers of before y saudy (s.g., mounty). The burster is not essensiate out on a recommendance of the product of the pro the set of vascular access. During baemodialysis, enovagarin sodium should be introduced into the arterial line of the circuit at the beginning of the dialysis session. The effect of this dose is vascular access coming internounaise; companies ocum removal en mource in the treatment on the circuit and the eighning of the displayed session. The viewer, if fibrin rings are found, for example after a longer than normal session, a further dose of 50 IU to 100 IU/kg (0.5 to 1 mg/kg) may be given. No data are available in patients using encoaparin sodium for prophylaxis or treatment and during haemodialysis sessions. Acute coronary syndrome: treatment of unstable angina and NSTEMI and treatment of acute STEMI. For treatment of unstable angina and NSTEMI, the recommended dose of enovanarin sodium is 100 III/kg (1 mg/kg) every 1 anguera un instrume and describer of decriber for the control of decriber of the control of the acetylsalicylic acid-naive patients) and a maintenance dose of 75–325 mg/day long-term regardless of treatment strategy. For treatment of acute STEMI, the recommended dose of enoxaparin sodium is a single intravenous (IV) bolus of 3,000 IU (30 mg) plus a 100 IUI/bg (1 mg/kg) SC dose followed by 100 IUI/bg (1 mg/kg) SC dose followed by 100 IUI/bg (1 mg/kg) administered SC every 12 hours (maximum 10,000 IU (100 mg) for each of the first two SC doses). Appropriate antiplatelet therapy such as oral acetylsalicytic acid (75 mg to 325 mg once daily) should be administered concomitantly unless contraindicated. The recommended duration of treatment is 8 days or until hospital discharge, whichever comes first. When administered in PRUPE-All is a doministreed concommanny unless contrainfuscaes. The recurrenteneou quarter to a supply of untertaining to supply the part of the prophylaxis of deep vein thrombosis and ischemic complications of unstable angina and non-Q-wave myocardial conjunction with a thromboylic, thickin specific or non-fibrin specific, encoagarin sould unstable the bettern 15 minutes before and 30 minutes at the start of thinnibytic infrarction. Its emperical formula is (S_pH_mM_pQ_pS_p) and molecular weight is 4500 g/mol (average). Structural formula is as shown:

therapy, For dosage in patients = 75 years of age, see paragraph "Eldery", For patients managed with PCI, if the last of dose of encoaparin social unstable and in the supply of the paragraph (and the supply of the supply of the paragraph (and the supply of the supply of the paragraph (and the supply of t enoxaparin sodium should be administered.

The safety and efficacy of enoxaparin sodium in paediatric population have not been established.

cuery for all indications except STEMI, no dose reduction is necessary in the elderly patients, unless kidney function is impaired. For treatment of acute STEMI in elderly patients ≥75 years of aga, an initial IV bolus must not be used. Initiate dosing with 75 IU/kg (0.75 mg/kg) SC every 12 hours (maximum 7,500 IU (75 mg) for each of the first two SC doses only. followed by 75 IU/kg (0.75 mg/kg) SC dosing for the remaining doses). For dosage in elderly patients with impaired kidney function

Limited data are available in patients with hepatic impairment and caution should be used in these natients.

Renal imnairment

Indication	Dosing régimen
Prophylaxis of venous thromboembolic disease	2,000 IU (20 mg) SC once daily
Treatment of DVT and PE	100 IU/kg (1 mg/kg) body weight SC once daily
Treatment of unstable angina and NSTEMI	100 IU/kg (1 mg/kg) body weight SC once daily
Treatment of acute STEMI (patients under 75)	1 x 3,000 IU (30 mg) IV bolus plus 100 IU/kg (1 mg/kg) body weight SC and then 100 IU/kg (1 mg/kg) body weight SC every 24 hours
Treatment of acute STEMI (patients over 75)	No IV initial bolus, 100 IU/kg (1 mg/kg) body weight SC and then 100 IU/kg (1 mg/kg) body weight SC every 24 hours

The recommended dosage adjustments do not apply to the haemodialysis indication. Moderate and mild renal impairment Although no dose adjustment is recommended in patients

ship clarication by proceedings absolute a source was a few and a second of the control of the c included in the pack of this medicine. IV (holus) injection (for acute STEMI indication only): For acute STEMI, treatment is to be initiated with a single IV holus injection immediately included by a Scripiction. For IV injection, either the multidose vial or prefiled syringe can be used. Encoaparin sodium should be administered through an IV line. It should not be mixed or coadministered with other medications. To avoid the possible mixture of encoaparin sodium with other drugs, the IV access chosen should be flushed with a sufficient amount of saline or dextrose solution prior to and following the IV bolus administration of enoxaparin sodium to clear the port of drug. Enoxaparin sodium may be safely Elimnature amount of saline or dextores solution in prof band following the IV books administration or encokapars socium to ear the perior or drug, encokapars socium no prof band following the IV books administration of the perior or drug, encokapars socium no set were perior or drug, encokapars socium polavated and an India of the IV book and administration of the IV books and the IV books and administration of the IV books and I administered if last SC administration was given more than 8 hours before balloon initiation. In order to assure the accuracy of the small volume to be injected, it is recommended to dilute the drug to 300 IU/mL (3 mg/mL). To obtain a 300 IU/mL (3 mg/mL) solution, using a 6,000 IU (60 mg) enoxaparin sodium prefilled syringe, it is recommended to use a 50 mil Based on the results of a population pharmacokinetic analysis, the enoxaparin sodium kinetic profile is not different in elderly subjects compared to younger subjects when renal initiation heag (i.e. using either normal saline solution (10 9%) of 5% decirose in water) as follows: Withdraw 30 mt. from the infusion bag with a syringe and discard the liquid. Inject the back of an excellence of the recognition of politic deposition of the recognition of the

Weight		Required dose 30 IU/kg (0.3 mg/kg)	Volume to inject when diluted to a final concentration of 300 IU
[Kg]	IU	[mg]	[mL]
45	1350	13.5	4.5
50	1500	15	5
55	1650	16.5	5.5
60	1800	18	6
65	1950	19.5	6.5
70	2100	21	7
75	2250	22.5	7.5
80	2400	24	8
85	2550	25.5	8.5
90	2700	27	9
95	2850	28.5	9.5
100	3000	30	10
105	3150	31.5	10.5
110	3300	33	11
115	3450	34.5	11.5
120	3600	36	12
125	3750		12.5
130	3900	39	13
135	4050	40.5	13.5

Switch between encogagerin sodium and oral anticoogucians.

Switch between encogagerin sodium and oral anticoogucians (VXA) Clinical monitoring and aboratory tests [profit motivin time expressed as the International Normalized Ratio (INR)] must be international sodium and vitarian's Anticiponistis (VXA) Clinical monitoring and aboratory tests [profit motivin time expressed as the International Normalized Ratio (INR)] must be internsified to monitor the effect of VXA. As there is an internal before the VXA reaches its maximum effect, encogagarin sodium therapy should be continued at a • Acute coronary syndrome:

- Constant does for as long as necessary in mode of the indication in the given at the time the next DOAC dose would be taken.

firming of puncture/catheter placement or removal to at least 24 hours. The 2 hours prepagative initiating of enoxagaring sodium 2 000 III (20 mg) is not compatible with neuraxial metabolic acidosis taking medicinal products known to increase notassium. Plasma notassium should be monitored requiative especially in patients at risk

A puncture-free interval of at least 24 hours shall be kept between the last injection of enoxaparin sodium at curative doses and the needle or catheter placement. For continuous techniques, a similar delay of 24 hours should be observed before removing the catheter. For patients with creatinine clearance [15-30] mL/min, consider doubling the timing of puncture/catheter placement or removal to at least 48 hours. Patients receiving the twice daily doses (i.e. 75 IU/kg (0.75 mg/kg) twice daily or 100 IU/kg (1 mg/kg) twice-daily) nominate products affection for the second encogarii sodium dose to allow a sufficient delay before catheter placement or removal as which affect haemostasis should be discontinued orier to encogarii sodium therapy unless delays are not a quarantee that neuranizal hematoma will be avoided. Likewise, consider not using monaparin sodium multi at least 4 hours after the spinal lepidural puncture or after the catheter has been removed. The delay must be based on a benefit-risk assessment considering both the risk for thrombosis and the risk for bleeding in the context of the rocedure and natient risk factors.

CONTRAINDICATIONS:

Hypersensitivity to enoxaparin sodium, heparin or its derivatives, including other low molecular weight heparins (LMWH) or to any of the excipients:

History of immune mediated negarin-induced thrombocytopenia (HTI) within the past 100 days or in the presence of circulating antibodies;

• Active clinically significant bleeding and conditions with a high risk of haemorrhage, including recent haemorrhagic stroke, gastrointestinal ulcer, presence of malignant neoplasm

at high risk of bleeding, recent brain, spinal or ophthalmic surgery, known or suspected gesophageal varices, arteriovenous malformations, vascular aneurysms or major in acute coronary syndrome due to the risk of bleeding,

 Spinal or epidural anaesthesia or loco-regional anaesthesia when enoxaparin sodium is used for treatment in the previous 24 hours. WARNING AND PRECAUTIONS:

Enoxaparin sodium cannot be used interchangeably (unit for unit) with other LMWHs. These medicinal products differ in their manufacturing process, molecular weights, specific anti-Na and anti-lla activities, units, dosage and clinical efficacy and safety. This results in differences in pharmacokinetics and associated biological activities (e.g. anti-thrombin activity, and platelet interactions). Special attention and compliance with the instructions for use specific to each proprietary medicinal product are therefore required.

Use of enoxaparin sodium in patients with a history of immune mediated HIT within the past 100 days or in the presence of circulating antibodies is contraindicated. Circulating antibodies may persist several years. Enoxaparin sodium is to be used with extreme caution in patients with a history (>100 days) of heparin-induced thrombocytopenia without

circulating antibodies. The decision to use enoxagarin sodium in such a case must be made only after a careful benefit risk assessment and after non-benarin alternative treatments. e considered (e.g. danaparoid sodium or lepirudin).

The risk of antibody-mediated HIT also exists with LMWHs. Should thrombocytopenia occur, it usually appears between the 5" and the 21" day following the beginning of enoxaparin

he risk of HIT is higher in postoperative patients and mainly after cardiac surgery and in patients with cancer. Therefore, it is recommended that the platelet counts be measured before the initiation of therapy with enoxaparin sodium and then regularly thereafter during the treatment. If there

re clinical symptoms suggestive of HT (any new episode of arterial and/or venous thromboemism, any painful skin lesion at the injection site, any allergic or anaphylacioid eactions on treatment), platelet count should be measured. Patients must be aware that these symptoms may occur and if so, that they should inform their primary care physician.

There are no clinical data for enoxaparin sodium in fertility. Animal studies did not show any effect on fertility. There are no clinical data for enoxaparin sodium in fertility. Animal studies did not show any effect on fertility. In practice, if a confirmed significant decrease of the platelet count is observed (30 to 50 % of the initial value), enoxaparin sodium treatment must be immediately discontinued and SIDE EFFECTS: he patient switched to another non-heparin anticoagulant alternative treatment

As with other anticoagulants, bleeding may occur at any site. If bleeding occurs, the origin of the baemorrhage should be investigated and appropriate treatment instituted.

- history of peptic ulcer.
- severe arterial hypertension
- recent diabetic retinopathy.
- neuro- or ophthalmologic surgery,
 concomitant use of medications affecting haemostasis

Laboratory restal
A Closes used for prophylaxis of venous thromboembolism, enoxaparin sodium does not influence bleeding time and global blood coagulation tests significantly, nor does it affect
A closes used for prophylaxis of venous thromboembolism, enoxaparin sodium affect in the prophylaxis of venous thromboembolism, enoxaparin sodium affecting time and global blood coagulation tests significantly, nor does it affect
A closes used for prophylaxis of venous thromboembolism, enoxaparin sodium afferting time (aFTT), and activated clotting time (AFTT) may occur

A feet and ACTE are not linearly correlated with increasing enoxaparin sodium afferting are usuals and unrelable for monitoring in a feet and ACTE are not linearly correlated with increasing enoxaparin sodium afferting and unrelable for monitoring in a feet and ACTE are not linearly correlated with increasing enoxaparin sodium afferting are usuals and unrelable for monitoring in a feet and ACTE are not linearly correlated with increasing enoxaparin sodium afferting time (aFTT), and activated clotting time (aFTT).

pinal/epidural anaesthesia or lumbar puncture must not be performed within 24 hours of administration of enoxaparin sodium at therapeutic doses. There have been cases of Skin and subcutaneous tissue disorder neurasial haematomas reported with the concurrent use of enoxaparin sodium dosage regimens 4,000 tU (40 mg) once daily or lower. The risk of these events are rare with enoxaparin sodium dosage regimens 4,000 tU (40 mg) once daily or lower. The risk of these events is higher with the use of post-operative Uncommon: Bullous dermatitis analysis. These deviations are take with changeant an anomal code graph principles above or the right of the control of the co interesting epitual a cantests, will use foundation to be a counted utility of the control of the presented epitual or spiral approximate, or in patients with a history of spiral surgery or spiral deferring. To reduce the potential risk of bleeding associated with the concurrent use of encouparin sodium and epitual or spiral an anesthesia analgesia or spiral approximate or spiral annotation. The present of the encouparin sodium and epitual or spiral annotation, the encouparin sodium is a facility of the encouparin sodium is described in the encouparin sodium. The encouparin sodium is described in the encouparin sodium. The encouparin is the encouparin in the encouparin is the encoupa calmeter of unitual puricure's to set per former where in a allucagularite livele of incursagains in source, in execution in processing and a comparison of the control of and/or bladder dystunction, instruct patients to report immediately if they experience any of the above signs or symptoms. If signs or symptoms of spinal hematoma are suspected, imitiate urgent diagnosis and treatment including consideration for spinal cord decompression even though such treatment may not prevent or reverse neurological sequelae.

Skin necrosis / cutaneous vasculitis kin necrosis and cutaneous vasculitis have been reported with LMWHs and should lead to prompt treatment discontinuation

rcutaneous coronary revascularization procedures

in minimize the risk of bleeding following the vascular instrumentation during the treatment of unstable anging NSTEMI and acute STEMI adhere precisely to the intervals commended between encoxparins odourn injection doses. It is important to achieve haemostasis at the puncture site after PCI. In case a doses of use, diverse device is used, the shareh and be doses, it is important to achieve haemostasis at the puncture site after PCI. In case a doses of use, diverse device is used, the shareh can be doses, it is unlikely that encoxparin sodium will be absorbed.

Management

Management 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

Acute infective endocarditis

Use of heparin is usually not recommended in patients with acute infective endocarditis due to the risk of cerebral haemorrhage. If such use is considered absolutely necessary, the has been determined that a second dose of protamine is required. After 12 hours of the enoxaparin sodium may be administrated greater than 8 hours previous to the protamine administration, or if has been determined that a second dose of protamine is required. After 12 hours of the enoxaparin sodium injection, protamine administration may not be required. However, even cision must be made only after a careful individual benefit risk assessment

meculanical prosined in near varies

STORAGE CONDITIONS:

STORAGE CONDITIONS: thrombosis have been reported in patients with mechanical prosthetic heart values who have received encoagan souther for thrombosis have been reported in patients with mechanical prosthetic heart values who have received encoagan souther for thromboprophylaxis. Confounding factors, including Shree below 25°C. Store protected from light. Do not refrigerate or freeze, underlying disease and insufficient clinical data, limit the evaluation of these cases. Some of these cases were pregnant women in whom thrombosis led to maternal and foetal

Pregnant women with mechanical prosthetic heart valves

The use of enoxaparin sodium for thromboprophylaxis in pregnant women with mechanical prosthetic heart valves has not been adequately studied. In a clinical study of pregnant

DOSAGE FORM AND PACKAGING AVAILABLE: women with mechanical prosthetic heart valves given enoxaparin sodium (100 LIV)q (1 mg/kg) twice daily) to reduce the risk of thromboembolism, 2 of 8 women developed closs resulting in blockage of the valve and leading to maternal and foetal death. There have been isolated postmarketing reports of valve thromboembolism, 2 of 8 women developed closs resulting in blockage of the valve and leading to maternal and foetal death. There have been isolated postmarketing reports of valve thromboembolism, 2 of 8 women developed closs resulting in blockage of the valve and leading to maternal and foetal death. There have been isolated postmarketing reports of valve thromboembolism, and the valves of the valve and leading to maternal and foetal death. There have been isolated postmarketing reports of valve thromboembolism, and the valves of the valves of the valves of the valve and leading to maternal and foetal death. There have been isolated postmarketing reports of valve thromboembolism, and the valves of the valves of the valves of the valve and leading to maternal and foetal death. There have been isolated postmarketing reports of valve thromboembolism, and the valves of the valves of the valve and leading to maternal and foetal death. There have been isolated postmarketing reports of valve thromboembolism, and the valves of the valves of the valve and leading to maternal and foetal death. There have been isolated postmarketing reports of valve thromboembolism, and the valves of the valve and leading to maternal and foetal death. There have been isolated postmarketing reports of valve thromboembolism. The valves with mechanical prosthetic heart valves with mechanic

No increased bleeding tendency is observed in the elderly with the prophylactic dosage ranges. Elderly patients (especially patients eighty years of age and older) may be at an increased risk for bleeding complications with the therapeutic dosage ranges. Careful clinical monitoring is advised and dose reduction might be considered in patients older than 75

. Renal impairment

In patients with renal impairment, there is an increase in exposure of enoxaparin sodium which increases the risk of bleeding. In these patients, careful clinical monitoring is advised and biological monitoring by an IAV a activity measurement might be considered. Enougarin sodium is not recommended for patients with end stage renal disease (creatinine clearance <15 mL/min) due to lack of data in this population outside the prevention of thrombus formation in extra corporeal circulation during haemodialysis. In patients with therapeutic and prophylactic dosage ranges. No dose adjustment is recommended in patients with moderate (creatinine clearance 30-50 mL/min) and mild (creatinine clear 50-80 mL/min) real impairment. evere renal impairment (creatinine clearance 15:30 ml/min), since exposure of enoxaparin sodium is significantly increased, a dosage adjustment is recommended for

Henatic impairment oxaparin sodium should be used with caution in patients with hepatic impairment due to an increased potential for bleeding. Dose adjustment based on monitoring of anti-Xa evels is unreliable in patients with liver cirrhosis and not recommended

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), which may lead to a higher risk of bleeding. Therefore, careful clinical monitoring is advised in these patients.

Dese patients are at higher risk for thromboembolism. The safety and efficacy of prophylactic doses in obese patients (BMI > 30 kg/m2) has not been fully determined and there is o consensus for dose adjustment. These patients should be observed carefully for signs and symptoms of thromboembolisn

is can suppress adrenal secretion of aldosterone leading to hyperkalaemia, particularly in patients such as those with diabetes mellitus, chronic renal failure, preexisting

Traceability

LMWHs are biological medicinal products. In order to improve the LMWH traceability, it is recommended that health care professionals record the trade name and batch number of the administered product in the patient file

- Systemic salicylates, acetylsalicylic acid at anti-inflammatory doses, and NSAIDs including ketorola

Other thrombolytics (e.g. alteplase, reteplase, streptokinase, tenecteplase, urokinase) and anticoagulants Concomitant use with caution:

The following medicinal products may be administered with caution concomitantly with enoxaparin sodium:

Other medicinal products affecting haemostasis such as:
- Platelet aggregation inhibitors including acetylsalicytic acid used at antiaggregant dose (cardioprotection), clopidogret, ticlopidine, and glycoprotein lib/lila antagonists indicated

Systemic glucocorticoids.

Medicinal products increasing potassium levels:

Medicinal products that increase serum potassium levels may be administered concurrently with enoxaparin sodium under careful clinical and laboratory monitoring.

PREGNANCY AND LACTATION:

Prennancy In humans, there is no evidence that enoxaparin crosses the placental barrier during the second and third trimester of pregnancy. There is no information available concerning the

Animal studies have not shown any evidence of foetotoxicity or teratogenicity. Animal data have shown that enoxaparin passage through the placenta is minimal.

Enoxaparin sodium should be used during pregnancy only if the physician has established a clear need.

Pregnant women receiving enoxaparin sodium should be carefully monitored for evidence of bleeding or excessive anticoagulation and should be warned of the haemorrhagic risk

Overall, the data suggest that there is no evidence for an increased risk of haemorrhage, thrombocytopenia or osteoporosis with respect to the risk observed in non-pregnant

women, other than that observed in pregnant women with prosthetic heart valves.

If an epidural anaesthesia is planned, it is recommended to withdraw enoxaparin sodium treatment before.

Breastfeeding

It is not known whether unchanged enoxaparin is excreted in human breast milk. In lactating rats, the passage of enoxaparin or its metabolites in milk is very low. The oral absorption of enoxaparin sodium is unlikely. Enoxaparin Becat can be used during breastfeeding.

Adverse reactions observed in clinical studies and reported in post-marketing experience are detailed below

equencies are defined as follows: very common (\geq 1/10); common (\geq 1/100 to < 1/10); uncommon (\geq 1/100); and very rare (< 1/10,000 to < 1/100); are (\geq 1/10,000 to < 1/1,000; and very rare (< 1/10,000 to rough (as not be estimated from available data). Within each system organ class, adverse reactions are presented in order of decreasing seriousness. Blood and the lymphatic system disorders

Common: Haemorrhage, haemorrhagic anaemia, thrombocytopenia, thrombocytosis Rare: Cases of immuno-allergic thrombocytopenia with thrombosis; in some of them thrombosis was complicated by organ infarction or limb ischaemia Immune system disorders

Common: Allergic reaction
Rare: Anaphylactic/Anaphylactoid reactions including shock

Nervous system disorders

ascular disorders

Uncommon: Henatocellular liver injury

OVERDOSE:

Accidental overdose with enoxaparin sodium after IV, extracorporeal or SC administration may lead to haemorrhagic complications. Following oral administration of even large

The anticoagulant effects can be largely neutralized by the slow IV injection of protamine. The dose of protamine depends on the dose of enoxaparin sodium injected; 1 mg protamine neutralizes the anticoaculant effect of 100 IU (1 mg) of enoxaparin sodium, if enoxaparin sodium was administered in the previous 8 hours, An infusion of 0.5 m

with high doses of protamine, the anti-Xa activity of enoxaparin sodium is never completely neutralized (maximum about 60%).

Manufactured by: Protech Telelinks

(A WHO-GMP Certified Co.) Mouza Ogli, Suketi Road, Kala Amb, Distt. Sirmour-173030 (H.P.) INDIA

windlas

Windlas Biotech Limited (A WHO GMP Certified Company) 40/1, Mohabewala Industrial Area, Dehradun-248110, Uttarakhand