CLEXANE®
enoxaparin

DOSAGE AND ADMINISTRATION GUIDE

This is intended for healthcare professionals use ONLY and must not be given to patients.

Prescribing information is located at the end of this document. Adverse events should be reported; adverse event reporting information for Clexane® is available on the inside back page

sanofi

MAT-IE-2101525 (v3.0) | August 2022

Clexane syringes

Clexane is available in two different types of pre-filled syringes.

The needle guard systems between these syringes differ. It is important that you know what syringe you are going to use and the correct technique before injecting your patient with Clexane.

Preventis syringe

Release of the safety mechanism when the plunger is depressed after the injection.

An audiable “click” confirms the activation of the safety mechanism

ERIS syringe

Automatic release of the safety mechanism when the plunger is fully depressed.

Needle completely covered by the protection cap immediately after the injection

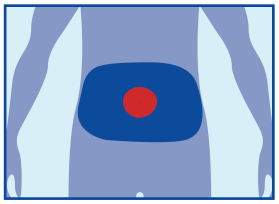
How to inject Clexane

Note: The instructions outlined below are for a matched fixed dose of Clexane, for instructions on adjusting the dose before injection, please refer to the SPC and PIL.

1. **Collect together the items that you will need: syringe, alcohol swab or soap and water, and a sharps container**

2. **Look at the label of the syringe and check the expiry date and that it is the correct dose.** Do not use if the expiry date has passed. Check the syringe is not damaged and the medicine in it is a clear solution. If not, use another syringe.

3. **Choose an area on either the left or the right side of the patient's abdomen, at least 5 cm away from the umbilicus and out towards the sides** – as shown by the dark blue colour.

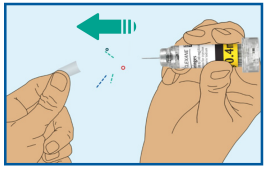


4. **Check the injection site** to see if the last injection caused any redness, change in the skin colour, swelling, oozing or is still painful.

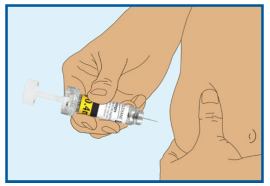
5. **Alternate the site** depending where the last injection was administered. The injection should preferably be made when the patient is lying down.

6. **Wash your hands, cleanse the area that** you will inject (do not rub the area).

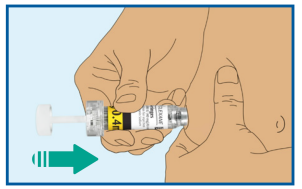
7. **Carefully remove the protective cap.** Do not press on the plunger before injecting to get rid of air bubbles as this can lead to a loss of medicine.



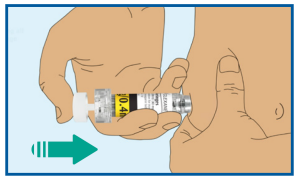
8. **Pinch a fold of the skin you are going to inject between your thumb and index finger.**



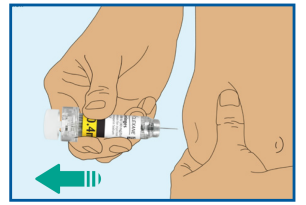
9. **The whole length of the needle should be introduced vertically (at a 90° angle) into the skin fold held between the thumb and index finger.**



10. **Press down gently but firmly on the plunger with your thumb until it can't go any further. Complete the subcutaneous injection, without releasing the skin fold until the injection is complete**



11. **This step is different between the ERIS and Preventis devices. Please go to page 1 for further information about activation of the needle guard safety system for the syringe you will inject.**



Follow this step if you are using the ERIS pre-filled syringe.

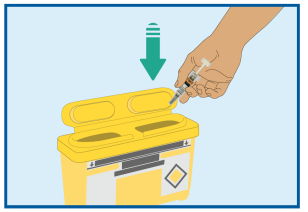
Remove the needle from the injection site by pulling it straight out. The safety shield will automatically engage as you pull the needle out of the skin and will cover the needle. Please note that the safety system only releases the protective sleeve when the syringe has been emptied by pressing the plunger all the way down. You can now let go of the skin fold.

Follow this step if you have the Preventis pre-filled syringe.

Remove the needle from the injection site by pulling it straight out. Face the needle away from you and others, then firmly push the plunger to activate the safety system. The protective sleeve will automatically cover the needle. You will hear an audible "click" to confirm the activation of the protective sleeve. You can now let go of the skin fold.

To avoid bruising, do not rub the injection site after administering the injection.

12. **Dispose of the used syringe into a sharps container and dispose of in accordance with local requirements.**



Prophylaxis of deep vein thrombosis (DVT) and pulmonary embolism (PE)[1]

Prophylaxis of DVT and PE

Patient population	Dose	Duration of therapy
Surgical patients at moderate risk of VTE	**2,000 IU (20 mg) SC once daily** Preoperative initiation 2 hours before surgery was proven effective	**A minimal period of 7–10 days whatever the recovery status (e.g. mobility) and continued until the patient no longer has signicantly reduced mobility**
Surgical patients at high risk of VTE	**4,000 IU (40 mg) SC once daily** Preferably started 12 hours before surgery	Extended prophylaxis of up to 5 weeks is recommended for major orthopaedic surgery and up to 4 weeks for abdominal or pelvic surgery for cancer
Medical patients (with an acute illness and reduced mobility)	**4,000 IU (40 mg) SC once daily**	**For at least 6 to 14 days whatever the recovery status (e.g. mobility) for a maximum of 14 days**

Please refer to the SPC for dosing in patients with renal impairment.
Please refer to the SPC for special warnings and precautions for use in patient with low body weight and patients who are obese.

Prevention of thrombus formation in extracorporeal circulation during haemodialysis[1]

Thrombus prevention during haemodialysis

Patient population	**Dose** (to be injected into the arterial side of the dialysis circuit at beginning of dialysis session)	Duration of therapy
During haemodialysis	**100 IU/kg (1 mg/kg) at beginning of dialysis session** **For those at high risk of haemorrhage, use a reduced dose:** 50 IU/kg (0.5 mg/kg) for double vascular access 75 IU/kg (0.75 mg/kg) for single vascular access	**Usually single dose sufficient for 4 hour dialysis session** A further dose of 50–100 IU/kg (0.5–1.0 mg/kg) may be given for a longer dialysis session if fibrin rings are found

Thrombus prevention during haemodialysis

Clexane single dose (to be injected into the arterial side of the dialysis circuit at beginning of dialysis session)

Clexane syringes 10,000 IU/mL (100 mg/mL)		
Body weight	**Dose**	**Injection volume (mL)**
40 kg	4,000 IU (40 mg)	0.40
45 kg	4,500 IU (45 mg)	0.45
50 kg	5,000 IU (50 mg)	0.50
55 kg	5,500 IU (55 mg)	0.55
60 kg	6,000 IU (60 mg)	0.60
65 kg	6,500 IU (65 mg)	0.65
70 kg	7,000 IU (70 mg)	0.70
75 kg	7,500 IU (75 mg)	0.75
80 kg	8,000 IU (80 mg)	0.80
85 kg	8,500 IU (85 mg)	0.85
90 kg	9,000 IU (90 mg)	0.90
95 kg	9,500 IU (95 mg)	0.95
100 kg	10,000 IU (100 mg)	1.00

Treatment of acute deep vein thrombosis (DVT) and pulmonary embolism (PE)[1]

CLEXANE® enoxaparin

Treatment of DVT and PE

Patient population	Dose	Duration of therapy
Uncomplicated patients (low risk of VTE recurrence)	**150 IU/kg (1.5 mg/kg) SC once daily** (see table on right)	**An average of 10 days** Oral anticoagulant therapy should be initiated when appropriate
Patients with high thromboembolic risk (such as obese, with symptomatic PE, cancer, recurrent VTE or proximal (iliac vein) thrombosis)	**100 IU/kg (1 mg/kg) SC twice daily** (see table on right)	**An average of 10 days** Oral anticoagulant therapy should be initiated when appropriate
Patients with active cancer (extended treatment and prevention of its recurrence) (carefully assess the thromboembolic and bleeding risks)	**100 IU/kg (1 mg/kg) SC twice daily loading dose, then 150 IU/kg (1.5 mg/kg) SC once daily maintenance dose** (see table on right)	**5-10 days loading, then up to 6 months maintenance** The benefit of continuous anticoagulant therapy should be reassessed after 6 months of treatment

VTE, venous thromboembolism

Clexane SC once daily dosing
150 IU/kg (1.5 mg/kg) OD

Clexane syringes 10,000 IU/mL (100 mg/mL)			Clexane syringes 15,000 IU/mL (150 mg/mL)		
Body weight	Dose	Injection volume (mL)	Body weight	Dose	Injection volume (mL)
40 kg	6,000 IU (60 mg)	0.60	70 kg	10,500 IU (105 mg)	0.70
45 kg	6,750 IU (67.5 mg)	0.675	75 kg	11,250 IU (112.5 mg)	0.76
50 kg	7,500 IU (75 mg)	0.75	80 kg	12,000 IU (120 mg)	0.80
55 kg	8,250 IU (82.5 mg)	0.825	85 kg	12,750 IU (127.5 mg)	0.86
60 kg	9,000 IU (90 mg)	0.90	90 kg	13,500 IU (135 mg)	0.90
65 kg	9,750 IU (97.5 mg)	0.975	95 kg	14,250 IU (142.5 mg)	0.96
			100 kg	15,000 IU (150 mg)	1.00

Clexane SC twice daily dosing
100 IU/kg (1 mg/kg) BD

Clexane syringes 10,000 IU/mL (100 mg/mL)			Clexane syringes 15,000 IU/mL (150 mg/mL)		
Body weight	Dose	Injection volume (mL)	Body weight	Dose	Injection volume (mL)
40 kg	4,000 IU (40 mg)	0.40	105 kg	10,500 IU (105 mg)	0.70
45 kg	4,500 IU (45 mg)	0.45	110 kg	11,000 IU (110 mg)	0.74
50 kg	5,000 IU (50 mg)	0.50	115 kg	11,500 IU (115 mg)	0.78
55 kg	5,500 IU (55 mg)	0.55	120 kg	12,000 IU (120 mg)	0.80
60 kg	6,000 IU (60 mg)	0.60	125 kg	12,500 IU (125 mg)	0.84
65 kg	6,500 IU (65 mg)	0.65	130 kg	13,000 IU (130 mg)	0.88
70 kg	7,000 IU (70 mg)	0.70	135 kg	13,500 IU (135 mg)	0.90
75 kg	7,500 IU (75 mg)	0.75	140 kg	14,000 IU (140 mg)	0.94
80 kg	8,000 IU (80 mg)	0.80	145 kg	14,500 IU (145 mg)	0.98
85 kg	8,500 IU (85 mg)	0.85	150 kg	15,000 IU (150 mg)	1.00
90 kg	9,000 IU (90 mg)	0.90			
95 kg	9,500 IU (95 mg)	0.95			
100 kg	10,000 IU (100 mg)	1.00			

In some cases it is not possible to achieve an exact dose due to the graduations on the syringe and so some
of the volumes recommended in this table have been rounded up to the nearest graduation.

Clexane dosing in renal impairment[1]

Clexane® dosing in renal impairment

Mild (CrCl 50–80 mL/min)

No recommended dose adjustment, but careful clinical monitoring is advised

Moderate (CrCl 30–50 mL/min)

No recommended dose adjustment, but careful clinical monitoring is advised

Estimating creatinine clearance (Cockcroft-Gault equation)[2]

$$\text{Constant} \times \frac{(140 - \text{age}) \times \text{weight (kg)}}{\text{Serum creatinine (micromol/L)}}$$

Where *constant* is *1.23* for men and *1.04* for women

Please refer to the SPC for further information

Severe (CrCl 15-30 mL/min)

Indication	Clexane® dosing
Prophylaxis of DVT and PE	2,000 IU (20 mg) SC once daily
Treatment of DVT and PE Extended treatment of DVT and PE in active cancer	100 IU/kg (1 mg/kg) body weight SC once daily
Treatment of UA and NSTEMI	100 IU/kg (1 mg/kg) body weight SC once daily
Treatment of acute STEMI (patients < 75 years old)	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 ≥ 75 years old)	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

End stage renal disease (CrCl < 15 mL/min)

Clexane® is not recommended due to lack of data in this population (outside of the prevention of thrombus formation in extra corporeal circulation during haemodialysis)

1. Clexane® Summary of Product Characteristics, February 2022.
2. https://secure.rlbuht.nhs.uk/sites/Antibiotic/SiteAssets/SitePages/Antimicrobials%20in%20renal%20impairment/Antimicrobials%20in%20renal%20impairment/Appendix%20One%20-%20useful%20equations.pdf (accessed August 2022)

Special warnings & precautions for use[1]

Clexane dosing in low body weight and obese

Extremes of body weight	
Low weight (Men < 57 kg and women < 45 kg)	**Obese** (BMI > 30 kg/m²)
Clinical monitoring advised. An increase in exposure of Clexane® 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.	Obese patients are at higher risk for thromboembolism. The safety and efficacy of prophylactic doses in obese patients 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.

Please refer to the SPC for further information

Contraindications[1]

Hypersensitivity to enoxaparin sodium, heparin or its derivatives, including low molecular weight heparins (LMWH) or any of the excipients. Recent (<100 days) history of immune mediated heparin-induced thrombocytopenia (HIT) 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/ suspected oesophageal varices, arteriovenous malformations, vascular aneurysms/ major intraspinal/ intracerebral vascular abnormalities. Spinal/ epidural/ loco-regional anaesthesia when enoxaparin sodium is used for treatment in the previous 24hrs.

Prescribing Information: Clexane® (enoxaparin sodium) & Clexane® Forte Solution for Injection in pre-filled syringes
Please refer to the Summary of Product Characteristics (SmPC) before prescribing

Presentations: Clexane® single dose pre-filled syringes containing either: 2,000 IU (20mg) enoxaparin sodium in 0.2ml, 4,000 IU (40mg) enoxaparin sodium in 0.4ml, 6,000 IU (60mg) enoxaparin sodium in 0.6ml, 8,000 IU (80mg) enoxaparin sodium in 0.8ml or 10,000 IU (100mg) enoxaparin sodium in 1ml. Clexane® Forte single dose pre-filled syringes containing either: 12,000 IU (120mg) enoxaparin sodium in 0.8ml or 15,000 IU (150mg) enoxaparin sodium in 1ml.

Indications: In adults for: prophylaxis of venous thromboembolic disease in moderate and high risk surgical patients, in particular those undergoing orthopaedic or general surgery including cancer surgery; prophylaxis of venous thromboembolic disease in medical patients with an acute illness (such as acute heart failure, respiratory insufficiency, severe infections or rheumatic diseases) and reduced mobility at increased risk of venous thromboembolism (VTE); treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery; extended treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of its recurrence in patients with active cancer; prevention of thrombus formation in extracorporeal circulation during haemodialysis; treatment of unstable angina and non ST- segment elevation myocardial infarction (NSTEMI), in combination with oral acetylsalicylic acid; treatment of acute ST-segment elevation myocardial infarction (STEMI) including patients to be managed medically or with subsequent percutaneous coronary intervention (PCI).

Dosage & Administration: Each pre-filled syringe is for single use only. ***Prophylaxis of VTE in Surgical Patients:*** With moderate risk of thromboembolism, recommended dose of enoxaparin sodium is 2,000 IU (20mg) once daily by subcutaneous (SC) injection. Initiation 2hrs before surgery was proven effective and safe in moderate risk surgery. Treatment should be maintained for at least 7-10 days whatever the recovery status (e.g. mobility) and should be continued until the patient no longer has significantly reduced mobility. In patients at high risk of thromboembolism, the recommended dose of enoxaparin sodium is 4,000 IU (40mg) once daily by SC injection preferably started 12hrs before surgery. Need for earlier than 12hrs enoxaparin sodium preoperative prophylactic initiation (e.g. high-risk patient waiting for a deferred orthopaedic surgery), the last injection should be administered no later than 12hrs prior to surgery and resumed 12hrs after surgery. For patients undergoing major orthopaedic surgery an extended thromboprophylaxis up to 5 weeks is recommended. For patients with high risk of VTE undergoing abdominal or pelvic surgery for cancer, extended thromboprophylaxis up to 4 weeks is recommended. ***Prophylaxis of VTE in Medical Patients:*** Recommended dose of enoxaparin sodium is 4,000 IU (40mg) once daily by SC injection. Treatment with enoxaparin sodium is prescribed for at least 6-14 days. Benefit is not established for treatment longer than 14 days. ***Treatment of DVT/PE:*** 150 IU/kg (1.5mg/kg) administered SC once daily should be used in uncomplicated patients with low risk of VTE recurrence. 100 IU/kg (1mg/kg) twice daily should be used in all other patients such as those with obesity, symptomatic PE, cancer, recurrent VTE or proximal (vena iliaca) thrombosis. The regimen should be selected based on individual assessment including evaluation of the thromboembolic risk and risk of bleeding. Enoxaparin sodium treatment is prescribed for an average period of 10 days. Oral anticoagulant therapy should be initiated when appropriate. ***Extended treatment of DVT and PE and prevention of its recurrence in patients with active cancer:*** physicians should carefully assess the individual thromboembolic and bleeding risks of the patient. The recommended dose is 100 IU/kg (1 mg/kg) twice daily by SCinjection for 5 to 10 days followed by a 150 IU/kg (1.5 mg/kg) once daily SC injection up to 6 months. The benefit of continuous anticoagulant therapy should be reassessed after 6 months of treatment. ***Treatment of Acute Coronary Syndromes:*** For treatment of unstable angina and NSTEMI, the recommended dose of enoxaparin sodium is 100 IU/kg (1mg/kg) every 12hrs by SC injection administered in combination with antiplatelet therapy. Treatment should be for a minimum of 2 days and until clinical stabilization (usual duration 2 to 8 days). Acetylsalicylic acid recommended for all patients without contraindications at an initial oral loading dose of 150–300mg (in acetylsalicylic acid-naive patients) and a maintenance dose of 75–325mg/day long-term. For treatment of acute STEMI, recommended dose of enoxaparin sodium is a single intravenous (IV) bolus of 3,000 IU (30mg) plus a 100 IU/kg (1mg/kg) SC dose followed by 100 IU/kg (1mg/kg) administered SC every 12hrs (maximum 10,000 IU (100mg) for each of the first 2 SC doses). Appropriate antiplatelet therapy such as oral acetylsalicylic acid (75mg to 325mg once daily) should be administered concomitantly unless contraindicated. Recommended duration of treatment is 8 days or until hospital discharge. When administered in conjunction with a thrombolytic (fibrin specific or non-fibrin specific), enoxaparin sodium should be given between 15 minutes before and 30 minutes after the start of fibrinolytic therapy. For patients managed with PCI, if the last dose of enoxaparin sodium SC was given less than 8hrs before balloon inflation, no additional dosing needed. If the last SC administration was given more than 8hrs before balloon inflation, an IV bolus of 30 IU/kg (0.3mg/kg) enoxaparin sodium should be administered. During haemodialysis: 100 IU/kg (1mg/kg) enoxaparin sodium introduced into arterial line of the circuit at beginning of dialysis. This dose is usually sufficient for a 4-hour session. If fibrin rings are found, e.g. after a longer session, a further 50 to 100 IU/kg (0.5 to 1mg/kg) may be given. In patients with high risk of haemorrhage reduce the dose to 50 IU/kg (0.5mg/kg) (double vascular access) or 75 IU/kg (0.75mg/kg) (single vascular access).

Special Populations: ***Elderly ≥75 years of age:*** For treatment of acute STEMI, an initial IV bolus must not be used. Initiate dosing with 75 IU/kg (0.75mg/kg) SC every 12hrs (maximum 7,500 IU (75mg) for each of the first 2 SC doses only, followed by 75 IU/kg (0.75mg/kg) SC dosing for the remaining doses). ***Paediatric***: Safety and efficacy not established. R***enal impairment:*** Dosage adjustment required for patients with severe renal impairment (creatinine clearance 15-30 mL/min). Not recommended for patients with end stage renal disease (creatinine clearance <15 mL/min. ***Hepatic Impairment:*** Limited data in this population therefore caution should be used.

Contraindications: Hypersensitivity to enoxaparin sodium, heparin or its derivatives, including low molecular weight heparins (LMWH) or any of the excipients. Recent (<100 days) history of immune mediated heparin-induced thrombocytopenia (HIT) 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/ suspected oesophageal varices, arteriovenous malformations, vascular aneurysms/ major intraspinal/ intracerebral vascular abnormalities. Spinal/ epidural/ loco-regional anaesthesia when enoxaparin sodium is used for treatment in the previous 24hrs.

Warnings and Precautions: Do not use interchangeably (unit for unit) with other LMWHs.

History of HIT (>100 days) without circulating antibodies**: Use with extreme caution in these patients and only after careful benefit-risk assessment and non- heparin alternative treatments are considered. **Monitoring of platelet counts:** In patients with cancer with a platelet count below 80 g/L, anticoagulation treatment can only be considered on a case-by-case basis and careful monitoring is recommended. There is a risk of antibody-mediated HIT, which is higher in postoperative patients and mainly after cardiac surgery and in patients with cancer. It is recommended that the platelet counts be measured before the initiation of therapy with enoxaparin sodium and then regularly thereafter during the treatment; or if clinical symptoms suggestive of HIT are experienced. Patients must be aware of the symptoms and told to inform their primary care physician if experienced. If a confirmed significant decrease of the platelet count is observed (30-50% of the initial value), enoxaparin sodium treatment must be immediately discontinued, and the patient switched to another non-heparin anticoagulant alternative treatment. **Haemorrhage**: Use with caution in conditions with increased potential for bleeding (e.g. impaired haemostasis, history of peptic ulcer, recent ischemic stroke, severe arterial hypertension, recent diabetic retinopathy, neuro- or ophthalmologic surgery, concomitant use of medications affecting haemostasis). **Laboratory tests:** Increases in activated partial thromboplastin time (aPTT) and activated clotting time (ACT) may occur at higher doses but not linearly correlated with increasing enoxaparin sodium antithrombotic activity. **Spinal/epidural anaesthesia or lumbar puncture:** must not be performed within 24hrs of administration of therapeutic doses of enoxaparin sodium; placement or removal of an epidural catheter or lumbar puncture is best performed when the anticoagulant effect of enoxaparin sodium is low. **Skin necrosis and cutaneous vasculitis:** have been reported with LMWHs and should lead to prompt treatment discontinuation. **Percutaneous coronary revascularization procedures:** To minimize the risk of bleeding following the vascular instrumentation during the treatment of unstable angina, NSTEMI and acute STEMI, adhere precisely to the intervals recommended between enoxaparin sodium injection doses. It is important to achieve haemostasis at the puncture site after PCI. In case a closure device is used, the sheath can be removed immediately. If a manual compression method is used, sheath should be removed 6 hours after the last IV/SC enoxaparin sodium injection. 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. **Acute infective endocarditis:** Use of heparin is usually not recommended in patients with this condition. **Mechanical prosthetic heart valves:** Enoxaparin sodium has not been adequately studied for thromboprophylaxis in patients (including in pregnancy) with mechanical prosthetic heart valves. **Elderly patients (especially >80 years old):** may be at increased risk of bleeding complications at therapeutic doses. **Hepatic impairment:** Enoxaparin sodium should be used with caution in these patients. In patients with liver cirrhosis dose adjustment based on monitoring of anti-Xa levels is unreliable and not recommended. **Renal impairment:** There is an increased risk of bleeding for these patients therefore careful clinical monitoring is advised and biological monitoring by anti-Xa activity measurement might be considered. Enoxaparin sodium is not recommended for patients with end stage renal disease. In patients with severe renal impairment (creatinine clearance 15-30 mL/min) a dosage adjustment is recommended for therapeutic and prophylactic dosage ranges. **Low body weight patients:** are at increased risk of bleeding at prophylactic and treatment dose ranges. Obese patients: are at higher risk for thromboembolism however there is no consensus for dose adjustment; these patients should be observed carefully. **Hyperkalaemia**: Heparins can suppress adrenal secretion of aldosterone leading to hyperkalaemia, particularly in patients such as those with diabetes mellitus, chronic renal failure, pre-existing metabolic acidosis, taking medicinal products known to increase potassium; plasma potassium should be monitored regularly especially in patients at risk. **Traceability**: 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. **Sodium**: For patients receiving doses 210mg/day, this medicine contains 24mg sodium, equivalent to 1.2% of the recommended maximum daily intake of sodium for an adult. **Pregnancy and Lactation:** 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. If an epidural anaesthesia is planned, it is recommended to withdraw treatment before. Enoxaparin sodium can be used during breastfeeding. **Interactions:** ***Not Recommended: Systemic salicylates, acetylsalicylic acid at anti-inflammatory doses, and NSAIDs including ketorolac. Other thrombolytics and anticoagulants. **Caution**: Platelet aggregation inhibitors including acetylsalicylic acid used at anti-aggregant dose (cardioprotection), clopidogrel, ticlopidine, and glycoprotein IIb/IIIa antagonists indicated in acute coronary syndrome due to the risk of bleeding, Dextran 40. Systemic glucocorticoids. Medicinal products increasing potassium levels.

Adverse Reactions: ***Very Common:*** Hepatic enzyme increases (mainly transaminases > 3 times the upper limit of normality). **Common**: Haemorrhage, haemorrhagic anaemia, thrombocytopenia, thrombocytosis, allergic reaction, headache, urticaria, pruritus, erythema, injection site haematoma / pain / other reaction (such as oedema, haemorrhage, hypersensitivity, inflammation, mass, pain, or reaction). **Uncommon**: Hepatocellular liver injury, bullous dermatitis, local irritation, skin necrosis at injection site. **Rare**: Eosinophilia, cases of immuno-allergic thrombocytopenia with thrombosis (in some cases thrombosis was complicated by organ infarction or limb ischaemia), anaphylactic/anaphylactoid reactions including shock, spinal/neuraxial haematoma resulting in varying degrees of neurologic injuries including long-term or permanent paralysis, cholestatic liver injury, alopecia, cutaneous vasculitis, skin necrosis, injection site nodules, osteoporosis following therapy > 3 months, hyperkalaemia. ***Not known:*** Acute generalized exanthematous pustulosis. Please refer to the SPCs for full details. **Legal Category:** POM. **Marketing Authorisation (MA) Numbers:** Clexane 2,000IU: PA540/97/4; Clexane 4,000IU: PA540/97/5; Clexane 6,000 IU: PA540/97/6; Clexane 8,000 IU: PA540/97/7; Clexane 10,000 IU: PA540/97/1; Clexane Forte 12,000 IU: PA540/97/8; Clexane Forte 15,000 IU: PA540/97/2 **MA Holder and further information is available on request from:** Sanofi Ireland Ltd., 18 Riverwalk, Citywest Business Campus, Dublin 24 or contact IEmedinfo@sanofi.com Tel: 01 403 5600. **Date of Preparation: February 2022 Document no. MAT-IE-2200013 (v1.0)**

Adverse events should be reported. Reporting forms and information can be found at: www.hpra.ie; E-mail: medsafety@hpra.ie
Adverse events can also be reported to Sanofi Ireland Ltd. Tel: 01 403 5600.
Alternatively, send via Email to IEPharmacovigilance@sanofi.com