



DOSAGE AND ADMINISTRATION GUIDE

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

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

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. Videos on the injection techniques for each device are available on the VTE matters website.

Preventis syringe



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

An audible "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



There are several different doses of CLEXANE, so the syringes may look slightly different from the ones shown in this booklet.



Remember that a video of "How to inject Clexane" is available for each device on VTE Matters.

www.vtematters.co.uk/hcp



How to use the Clexane pre-filled Preventis syringe

This video is produced and funded by Sanofi. This video is intended for HCPs who prescribe and administer Clexane (enoxaparin).

How to use the Clexane pre-filled Eris syringe

This video is produced and funded by Sanofi. This video is intended for HCPs who prescribe and administer Clexane (enoxaparin).

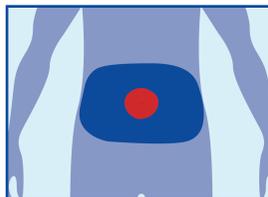
How to inject Clexane

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).

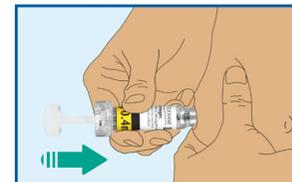
7 Carefully remove the protective cap. Do not press on the plunger before injecting to get rid of air bubbles as this can lead to a loss of medicine.



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



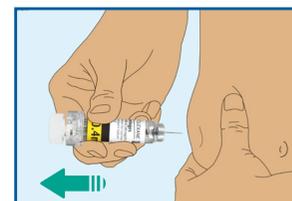
9 The whole length of the needle should be introduced vertically (at a 90° angle) into the skin fold held between the thumb and index finger.



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 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 significantly 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.

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 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. Please note, the graduations on the Clexane Forte syringes are 0.2mL.

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
$\frac{\text{Constant} \times (140 - \text{age}) \times \text{weight (kg)}}{\text{Serum creatinine (micromol/L)}}$
<p>Where <i>constant</i> is 1.23 for men and 1.04 for women</p>

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 in combination with oral acetylsalicylic acid	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)	

Extremes of body weight	
Low weight (Men < 57 kg and women < 45 kg)	Obese (BMI > 30 kg/m ²)
<p>Clinical monitoring advised.</p> <p>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.</p>	<p>Obese patients are at higher risk for thromboembolism.</p> <p>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.</p>

Please refer to the SPC for further information

Contraindications¹

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 or suspected oesophageal varices, arteriovenous malformations, vascular aneurysms or major intraspinal or intracerebral vascular abnormalities. Spinal or epidural anaesthesia or loco-regional anaesthesia when enoxaparin sodium is used for treatment in the previous 24 hours. Multiple dose vials contain benzyl alcohol therefore contraindicated in: those with hypersensitivity to benzyl alcohol and newborns or premature neonates.

During this time of predominantly virtual interactions Sanofi would like to stay in touch with you !



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Scan the QR code to register at:
<https://www.sanofi.co.uk/en/about-us/sanofi-in-the-uk/staying-in-touch>



Prescribing Information: Clexane® (Enoxaparin sodium)

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentations: *Clexane® Syringes:* single dose, pre-filled syringes containing: enoxaparin sodium (IU) in water (ml) in the quantities; 2,000IU (20mg) in 0.2ml, 4,000IU (40mg) in 0.4ml, 6,000IU (60mg) in 0.6ml, 8,000IU (80mg) in 0.8ml or 10,000IU (100mg) in 1ml. *Clexane® Forte Syringes:* single dose, pre-filled syringes containing either: 12,000IU (120mg) enoxaparin sodium in 0.8ml or 15,000IU (150mg) enoxaparin sodium in 1ml. *Clexane® Multidose vial:* containing 30,000IU (300mg) enoxaparin sodium in 3ml solution for injection for single patient use.

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 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 extra corporeal 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: Clexane® should not be administered by the intramuscular route.

Prophylaxis in Surgical Patients: With moderate risk of thromboembolism, recommended dose is 2,000IU (20mg) once daily by subcutaneous (SC) injection. Initiation 2 hours before surgery was proven effective and safe in moderate risk surgery. Treatment should be maintained for at least 7–10 days and until the patient no longer has significantly reduced mobility. In patients at high risk of thromboembolism, the recommended dose of is 4,000IU (40mg) once daily by SC injection preferably started 12 hours before surgery. If there is a need for preoperative prophylactic initiation earlier than 12 hours (e.g. high risk patient waiting for a deferred orthopaedic surgery), the last injection should be administered no later than 12 hours prior to surgery and resumed 12 hours 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 in Medical Patients: Recommended dose is 4,000IU (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 and PE:** 150IU/kg (1.5mg/kg) administered SC once-daily should be used in uncomplicated patients with low risk of VTE recurrence. 100IU/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. In the 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 100IU/kg (1mg/kg) administered twice daily by SC injections for 5–10 days, followed by a 150IU/kg (1.5mg/kg) once daily SC injection up to 6 months. The benefit of continuous anticoagulant therapy should be reassessed after 6 months of treatment. **During haemodialysis:** 100IU/kg (1mg/kg) Clexane® 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 50–100IU/kg (0.5–1mg/kg) may be given. In patients with high risk of haemorrhage reduce the dose to 50IU/kg (0.5mg/kg) (double vascular access) or 75IU/kg (0.75mg/kg) (single vascular access).

Treatment of Acute Coronary Syndromes: For treatment of unstable angina and NSTEMI, the recommended dose is 100IU/kg (1mg/kg) every 12 hours by SC injection administered in combination with antiplatelet therapy. Treatment should be for a minimum of 2 days and until clinical stabilization (usual duration 2–8 days). Acetylsalicylic acid recommended for all patients without contraindications at an initial oral loading dose of 150–300mg (in acetylsalicylic acid-naïve 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 3,000IU (30mg) plus a 100IU/kg (1mg/kg) SC dose followed by 100IU/kg (1mg/kg) administered SC every 12 hours (maximum 10,000IU (100mg) for each of the first 2 SC doses). Appropriate antiplatelet therapy such as oral acetylsalicylic acid (75–325mg 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 8 hours before balloon inflation, no additional dosing needed. If the last SC administration was given more than 8 hours before balloon inflation, an IV bolus of 30IU/kg (0.3mg/kg) enoxaparin sodium should be administered.

Special populations: **Elderly:** For treatment of acute STEMI in elderly ≥ 75 years of age, an initial IV bolus must not be used. Initiate dosing with 75IU/kg (0.75mg/kg) SC every 12 hours (maximum 7,500IU (75mg) for each of the first two SC doses only, followed by 75IU/kg (0.75mg/kg) SC dosing for the remaining doses).

Children: Safety and efficacy not established. **Renal impairment:** Not recommended for patients with end stage renal disease. Dosage adjustment required for patients with severe renal impairment. See SmPC for full details. **Hepatic impairment:** Limited data. 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 or suspected oesophageal varices, arteriovenous malformations, vascular aneurysms or major intraspinal or intracerebral vascular abnormalities. **Multiple dose vials contain benzyl alcohol** therefore contraindicated in: those with hypersensitivity to benzyl alcohol and newborns or premature neonates.

Warnings and Precautions: Do not use interchangeably (unit for unit) with other LMWHs. In order to improve the LMWH traceability, healthcare professionals should record the trade name and batch number administered. **Heparin-induced Thrombocytopenia:** Use with extreme caution in patients with a history (>100 days) of HIT without circulating antibodies, only after careful benefit-risk assessment and after non-heparin alternative treatments are considered; platelet counts should be measured before and regularly thereafter during the treatment and patients should be warned of symptoms. 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. **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). **Laboratory tests:** Increases in activated partial thromboplastin time (aPTT), and activated clotting time (ACT) may occur at higher doses but not linearly correlated with dose. Spinal/epidural anaesthesia or lumbar puncture must not be performed within 24 hours 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. **Severe skin reactions:** Skin necrosis, cutaneous vasculitis and acute generalised

exanthematous pustulosis have been reported with LMWHs. At the time of prescription, patients should be advised of the symptoms and monitored closely, and any signs should lead to prompt treatment discontinuation. **Cardiac precautions:** Following vascular instrumentation during the treatment of unstable angina, NSTEMI and acute STEMI: adhere precisely to the recommended dosing intervals; 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; The site should be observed for signs of bleeding or hematoma. Use of heparin is usually not recommended in patients with acute infective endocarditis. Enoxaparin sodium has not been adequately studied for thromboprophylaxis in patients (including in pregnancy) with mechanical prosthetic heart valves. **Special populations:** Elderly patients, and those with renal or hepatic impairment may be at increased risk of bleeding at treatment doses. **Weight:** 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. **Sodium:** For patients receiving doses higher than 210mg/day, this medicine contains more than 24mg sodium, equivalent to 1.2% of WHO recommended maximum daily intake. **Pregnancy:** Enoxaparin sodium should be used during pregnancy only if the physician has established a clear need. As benzyl alcohol may cross the placenta, it is recommended to use a formulation that does not contain benzyl alcohol. **Interactions: Not Recommended:** Systemic salicylates, acetylsalicylic acid at anti-inflammatory doses, and NSAIDs including ketorolac. Other thrombolytics (e.g. alteplase, reteplase, streptokinase, tenecteplase, urokinase) 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: For all indications, **Very Common:** Hepatic enzyme increases (mainly transaminases >3x the upper limit of normal), **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 immune-allergic thrombocytopenia with thrombosis (in some, thrombosis was complicated by organ infarction or limb ischaemia), 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 usually occurring at the injection site (these phenomena have been usually preceded by purpura or erythematous plaques, infiltrated and painful). Osteoporosis (following therapy >3 months), hyperkalaemia. **Frequency not known:** Acute generalised exanthematous pustulosis. Prescribers should consult the SmPC in relation to other adverse reactions.

Legal Category: POM.

Marketing Authorisation (MA) Holder: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK.

MA numbers: Clexane® Forte Syringes: PL 04425/0185, Clexane® Multidose Vials: PL 04425/0186, Clexane® Syringes: PL 04425/0187.

UK list prices: 10x prefilled syringes: 2,000IU: £20.86, 4,000IU: £30.27, 6,000IU: £39.26, 8,000IU: £55.13, 10,000IU: £72.30, 12,000IU: £87.93, 15,000IU: £99.91. 1x Multidose Vial: £21.33.

For more information please contact: Sanofi Medical Information, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com.

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Adverse events should be reported.
Reporting forms and information can be found at
www.yellowcard.mhra.gov.uk
Adverse events should also be reported to Sanofi

Tel: 0800 0902314.
Alternatively, send via email to
UK-drugsafety@sanofi.com