CLEXANE® (ENOXAPARIN) DOSING & ADMINISTRATION

Clexane Syringe

Administration

VTE Prophylaxis

VTE Treatment

Renal impairment

Special Warnings

Contraindications

This is intended for healthcare professionals use ONLY and must not be given to patients. A separate guide for patients is available. This material is only intended to be viewed online. Click here for Prescribing information

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

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Clexane syringe

Clexane is available in a pre-filled syringe.

It is important you familiarise yourself with the syringe and the correct technique before injecting your patient with Clexane. Videos on the injection techniques are available on the Sanofi Campus website.

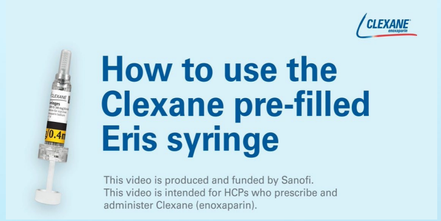
ERIS syringe

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

Needle completely covered by the protection cap immediately after the injection

Remember that a video of "How to inject Clexane" is available on Sanofi Campus.

Click here to access the video



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

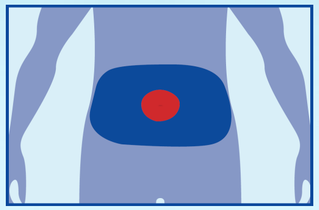
Administration of Clexane

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.

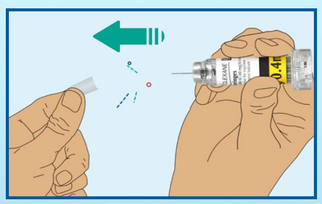


4. **Check the injection site** to see if the last injection caused any redness, change in the skin colour, swelling, oozing or is still painful.

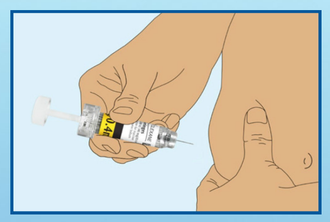
5. **Alternate the site** depending where the last injection was administered. The injection should preferably be made when the patient is lying down.

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

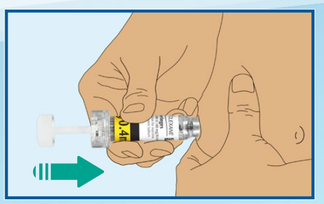
7. **Carefully remove the protective cap.** Do not press on the plunger before injecting to get rid of air bubbles as this can lead to a loss of medicine.



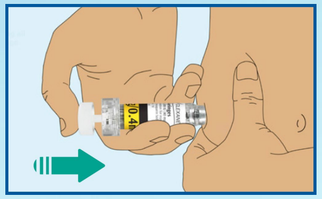
8. **Pinch a fold of the skin you are going to inject between your thumb and index finger.**



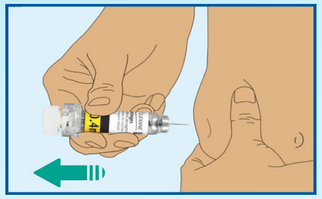
9. **The whole length of the needle should be introduced vertically (at a 90° angle) into the skin fold held between the thumb and index finger.**



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**



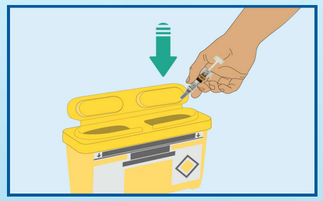
11. **Please go to page 1 for further information about activation of the needle guard safety system.**



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.

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 (20mg) 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 patients 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 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 the 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 (40 mg)	0.45
50 kg	5,000 IU (40 mg)	0.50
55 kg	5,500 IU (40 mg)	0.55
60 kg	6,000 IU (40 mg)	0.60
65 kg	6,500 IU (40 mg)	0.65
70 kg	7,000 IU (40 mg)	0.70
75 kg	7,500 IU (40 mg)	0.75
80 kg	8,000 IU (40 mg)	0.80
85 kg	8,500 IU (40 mg)	0.85
90 kg	9,000 IU (40 mg)	0.90
95 kg	9,500 IU (40 mg)	0.95
100 kg	10,000 IU (40 mg)	1.00

For healthcare professionals only. 1. Clexane® Summary of Product Characteristics, February 2022.

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

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 (1.5mg/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)	0.7
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 (1mg/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)	0.7
45 kg	4,500 IU (40 mg)	0.45	110 kg	11,000 IU (110 mg)	0.74
50 kg	5,000 IU (40 mg)	0.50	115 kg	11,500 IU (115 mg)	0.78
55 kg	5,500 IU (40 mg)	0.55	120 kg	12,000 IU (120 mg)	0.80
60 kg	6,000 IU (40 mg)	0.60	125 kg	12,500 IU (125 mg)	0.84
65 kg	6,500 IU (40 mg)	0.65	130 kg	13,000 IU (130 mg)	0.88
70 kg	7,000 IU (40 mg)	0.70	135 kg	13,500 IU (135 mg)	0.90
75 kg	7,500 IU (40 mg)	0.75	140 kg	14,000 IU (135 mg)	0.94
80 kg	8,000 IU (40 mg)	0.80	145 kg	14,500 IU (145 mg)	0.98
85 kg	8,500 IU (40 mg)	0.85	150 kg	15,000 IU (150 mg)	1.00
90 kg	9,000 IU (40 mg)	0.90			
95 kg	9,500 IU (40 mg)	0.95			
100 kg	10,000 IU (40 mg)	1.00			

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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[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)

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

Where constant is 1.23 for men and 1.04 for women

Please refer to the SPC for further information

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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)

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Special warnings & precautions for use[1]
Clexane dosing in low body weight and obese

EXTREMES OF BODY WEIGHT	
Low weight patients (Men <57 kg and women <45 kg)	**Patients with obesity** (BMI >30 kg/m^2)
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 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 signs and symptoms of thromboembolism.

Please refer to the SPC for further information
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Contraindications[1]

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 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

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