



A WORLD OF EXPERIENCE IN ONE ANTICOAGULANT

Clexane®, the reference antithrombotic

- With more than 30 years of clinical experience¹
- Chosen by physicians for over 900 million patients worldwide²

Delivering antithrombotic management you can rely on for your diverse patients' needs

References :
1. European Medicines Agency (EMA), Assessment report, referral under article 30 of Directive 2001/83/EC, Lovenox and associated names 15 December 2016, EMA/13417/2017. 2. Sanofi. Data on file. Patient exposure from marketed use of enoxaparin. July 2021.

CLEXANE® Abbreviated Prescribing Information (Version V03-20)

- NAME AND PRESENTATION:** CLEXANE reg no. IC 32/43 (N) is available as pre-filled syringes containing 20 mg, 40 mg, 60 mg or 80 mg of enoxaparin sodium.
- THERAPEUTIC INDICATIONS:** *20 mg and 40 mg:* prophylaxis of venous thrombo-embolic disease in patients undergoing an orthopedic or general surgery procedure including cancer surgery, with a moderate or high risk of thromboembolism and prevention of clotting in the extra-corporeal circulation during hemodialysis. *40 mg:* Prophylaxis of venous thromboembolism in medical patients bedridden due to acute illnesses including acute heart failure (NYHA class III or IV), acute respiratory failure, acute infectious disease or acute rheumatic disease. *60 mg and 80 mg:* curative treatment of established DVT, with or without PE, without signs of clinical severity, excluding PE likely to require treatment with a thrombolytic agent or by surgery; treatment of unstable angina and acute non-Q-wave MI, in combination with aspirin; treatment of acute ST-segment elevation MI, in combination with a thrombolytic agent in patients eligible or not for subsequent coronary angioplasty.
- POSOLGY AND METHOD OF ADMINISTRATION:** *Prophylactic of VTE in surgery moderate risk:* the recommended dose is 20 mg or 40 mg SC OD, given 2 hours before surgery. Duration of treatment is usually for 7 to 10 days. *high risk:* 40 mg SC OD, initiated 12 hours prior to surgery or 30 mg BID, initiated 12 to 24 hours after surgery. *Patients with high VTE risk: major orthopedic surgery:* for thromboprophylaxis up to 5 weeks cancer surgery; for thromboprophylaxis up to 4 weeks *Prophylactic of DVT in acute medical conditions:* 40 mg SC OD for 6 to 14 days. *Prevention of clotting in extracorporeal circulation/hemodialysis (IV bolus):* An initial dose is 1 mg/kg in the arterial line of the dialysis circuit at the beginning of the session, suitable for hemodialysis sessions of 4 hours or less. *Curative treatment of DVT with or without PE, without signs of clinical severity:* can be administered either as a 15 mg/kg SC OD or as 1 mg/kg SC BID. In complicated thromboembolic disorders, a dose of 1 mg BID is recommended. Treatment duration should not exceed 10 days. *Curative treatment of unstable angina/non-Q-wave MI:* 1 mg/kg SC BID at 12-hour intervals, in combination with aspirin. Duration of treatment is about 2 to 8 days. Must not be administered by IM route.
- CONTRA-INDICATIONS:** Must not be used in the following situations: hypersensitivity to enoxaparin sodium, heparin or its derivatives, including the other LMWHs, bleeding or tendency to bleed related to impaired hemostasis (a possible exception to this contraindication may be disseminated intravascular coagulation, when not related to heparin treatment), organic lesion likely to bleed, clinically significant active major bleeding and conditions with a high risk of uncontrolled hemorrhage, including recent hemorrhagic stroke, history of immune mediated heparin-induced thrombocytopenia (HIT) within the past 100 days or in the presence of circulating antibodies. Must not be used at curative doses in: intracerebral hemorrhage, spinal or epidural anesthesia (must never be performed in patients under curative LMWH treatment).
- SPECIAL WARNINGS AND PRECAUTIONS FOR USE:** Not advisable at curative doses in: acute extensive ischemic stroke, with or without impaired consciousness; acute infectious endocarditis; mild to moderate kidney failure; at prophylactic doses in: severe renal failure; during the first 24 hours following intracerebral hemorrhage; spinal/epidural anesthesia in patients given preventive treatment with LMWH; risk of HIT; coronary angioplasty revascularization procedure; pregnant women with mechanical prosthetic heart valves; children. Used with caution in hemorrhage; mechanical prosthetic heart valves; renal and hepatic impairment; low weight and obese patients. Clinical monitoring and laboratory tests is considered especially for platelet, prothrombin time, anti-factor Xa activity, and activated partial thromboplastin time (aPTT). Dose adjustment is recommended in severe renal impairment patients.
- DRUG INTERACTIONS:** Drugs may promote hyperkalemia (potassium salts, potassium-sparing diuretics, conversion enzyme inhibitors, ARBs, NSAIDs, heparins (LMWHs or UFHs), ciclosporin and tacrolimus, trimethoprim). Should be discontinued these agents unless there are essential: systemic salicylates, acetylsalicylic acid, NSAIDs, Dextran 40, ticlopidine, clopidogrel, systemic glucocorticoids, thrombolytics, anticoagulants, and other anti-platelet agents including glycoprotein IIb/IIIa antagonists.
- PREGNANCY AND LACTATION:** *Pregnancy:* Only if a clear need is established. Avoid breast-feeding.
- UNDESIRABLE EFFECTS:** *Very common:* haemorrhages, thrombocytosis hepatic enzymes increase (mainly transaminases). *Common:* thrombocytopenia, allergic reaction, urticaria, pruritus, erythema, injection site haematoma, injection site pain, and other injection site reaction.
- OVERDOSAGE:** Accidental over dosage after IV, extracorporeal or SC administration may lead to hemorrhagic complications. In case of hemorrhage, certain patients can be treated with protamine sulfate (as an antidote).
- PHARMACOLOGICAL PROPERTIES:** Antithrombotic agents: heparin group. ATC Code: B01AB05

For more information, please see full prescribing information.

โปรดอ่านรายละเอียดเพิ่มเติมในเอกสารกำกับยา และเอกสารอ้างอิงฉบับสมบูรณ์

เลขที่ทะเบียนยา: IC 32/43 (N) / ใบอนุญาตเลขที่ บพ. 638/2565
MAT-TH-2200434 V1.0 APR2022

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