AROVI® 2,000 IU (20 mg)/0.2 ml; 4,000 IU (40 mg)/0.4 ml; 6,000 IU (60 mg)/0.6 ml; 8,000 IU (80 mg)/0.8 ml; 10,000 IU (100 mg)/1 ml; 12,000 IU (120 mg)/0.8ml; 15,000 IU (150 mg)/1 ml.

Refer to Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Each prefilled syringe contains 20/ 40/ 60/ 80/ 100/ 120/ 150 mg enoxaparin sodium (equivalent to 2,000/ 4,000/ 6,000/ 8,000/ 10,000/ 12,000/ 15,000 IU anti-Xa activity). **Indications:** Prophylaxis of venous thromboembolic disease in moderate and high-risk surgical patients. Prophylaxis of venous thromboembolic disease in medical patients with an acute illness and reduced mobility. 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. Acute coronary syndrome: 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). **Contraindications:** Hypersensitivity to enoxaparin sodium, heparin or its derivatives, including other low molecular weight heparins (LMWH) or to any of the excipients listed in the SmPC; History of immune mediated heparin-induced thrombocytopenia (HIT) 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 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. **Warnings and Precautions:** Name and batch number should be clearly recorded. Enoxaparin sodium cannot be used interchangeably with other LMWHs due to differences in pharmacokinetics and associated biological activities (e.g. antithrombin activity, and platelet interactions). Extreme caution required in patients with a history (>100 days) of heparin-induced thrombocytopenia (HIT) without circulating antibodies. Monitor platelet count in cancer patients with counts below 80 g/L, when initiating enoxaparin, and regularly during treatment. Haemorrhage may occur. At higher doses increases in a PTT (partial thromboplastin time) and ACT (activated clotting time) may occur, these increases are unreliable and unsuitable for monitoring anticoagulant activity. Do not perform spinal/ epidural anaesthesia or lumbar puncture within 24 hours of enoxaparin administration at treatment doses. Discontinue use if skin necrosis/cutaneous vasculitis occur. Adhere precisely to dosing intervals with percutaneous coronary revascularisation procedures. Usually not recommended in acute infective endocarditis due to risk of cerebral haemorrhage. Use not adequately studied in patients with mechanical heart valves; pregnant women may be at higher risk for thromboembolism. **Special Populations:** Carefully monitor elderly patients receiving therapeutic doses; consider dose reductions in patients >75 years treated for STEMI. The safety and efficacy have not been established in children. Monitor carefully in renal impairment. Dose reduction recommended in severe renal impairment (creatinine clearance 15-30 mL/min). Not recommended in end stage renal disease. No dose adjustment recommended in patients with mild or moderate renal impairment. Use with caution in hepatic impairment. Careful clinical monitoring advised in women <45 kg and men <57 kg.The safety and efficacy of prophylactic doses in obese patients has not been fully determined. Observe carefully for thromboembolism. Hyperkalaemia; heparins can suppress aldosterone leading to hyperkalaemia; monitor potassium levels, especially in patients at risk. Acute generalised exanthematous pustulosis (AGEP); monitor closely and withdraw immediately if signs/ symptoms occur. Consider alternative treatment as appropriate. **Interactions:** It is recommended that some agents which affect haemostasis should be discontinued prior to enoxaparin sodium therapy unless strictly indicated. If the combination is indicated, enoxaparin sodium should be used with careful clinical and laboratory monitoring when appropriate. **Pregnancy:** Enoxaparin sodium should be used during pregnancy only if the physician has established a clear need. Use in pregnant women with prosthetic heart valves is not recommended. **Lactation:** AROVI can be used during breastfeeding. **Fertility:** No clinical data. **Undesirable effects: Very common:** Hepatic enzyme increases. **Common**: Haemorrhage, haemorrhagic anaemia, thrombocytopenia, thrombocytosis, allergic reaction, headache, urticaria, pruritus, erythema, injection site haematoma, injection site pain, oedema, haemorrhage, hypersensitivity, inflammation, mass. **Rare**: Anaphylaxis, immuno-allergic thrombocytopenia with thrombosis, spinal or neuraxial haematoma including long-term or permanent paralysis. Skin necrosis. Hyperkalaemia. **Not known:** Acute generalised exanthematous pustulosis (AGEP).

Please consult the SmPC in relation to other adverse reactions.

Storage: Store below 25°C. Do not freeze.

Legal Category: **POM**

MA Holder: Laboratorios Farmacéuticos ROVI, S.A. Julián Camarillo, 35, 28037 – Madrid, Spain.

Marketing Authorisation Numbers:

AROVI® 2,000 IU (20 mg)/0.2 mL - PL 15406/0007
AROVI® 4,000 IU (40 mg)/0.4 mL - PL 15406/0008
AROVI® 6,000 IU (60 mg)/0.6 mL - PL 15406/0009
AROVI® 8,000 IU (80 mg)/0.8 mL - PL 15406/0010
AROVI® 10,000 IU (100 mg)/1 mL- PL 15406/0002
AROVI® 12,000 IU (120 mg)/0.8 mL - PL 15406/0006
AROVI® 15,000 IU (150 mg)/1 mL - PL 15406/0003

Basic NHS prices:

AROVI® 2,000 IU (20 mg)/0.2 mL x 10, £15.65.
AROVI® 4,000 IU (40 mg)/0.4 mL x 10, £22.70.
AROVI® 6,000 IU (60 mg)/0.6 mL x 10, £29.45.
AROVI® 8,000 IU (80 mg)/0.8 mL x 10, £41.35.
AROVI® 10,000 IU (100 mg)/1 mL x 10, £54.23.
AROVI® 12,000 IU (120 mg)/0.8 mL x 10, £65.95
AROVI® 15,000 IU (150 mg)/1 mL x 10, £74.93

Last date of revision: December 2025.

UK-ENOX-UK-25-110001

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellowcard in the Google Play or Apple App Store.
Adverse events should also be reported to uk-pharmacovigilance@rovi.com or by telephone +44 (0) 757 070 1132.