**The right anticoagulant. For the right patient. At the right time.**

# Ovinox™

FROM SCIENCE TO BEDSIDE—TRUSTED FOR CARE, PROVEN BY EVIDENCE.

Hepasonica Middle East

## WHAT'S OVINOX?

Ovinox™ is the **world's first ovine-derived** low molecular weight heparin (LMWH).

A safe and effective alternative for patients seeking non-porcine options in anticoagulation therapy.

## INTENDED USE

Intended for prevention and treatment of thromboembolic disorders.

Integral for use across venous thromboembolism (VTE), deep vein thrombosis (DVT), with or without pulmonary embolism (PE), unstable angina and non-ST elevation myocardial infarction (NSTEMI), STEMI treatment in non-PCI candidates.
Thromboprophylaxis in high-risk medical and trauma patients.

## HOW IT WORKS?

Ovinox™ enhances antithrombin III activity, inhibiting factor Xa and preventing clot formation.
This dual-action mechanism reduces thrombin generation and fibrin formation, lowering the risk of serious thrombotic events.

## WHY OVINOX?

**Ethically Distinct**
The only enoxaparin derived entirely from ovine (sheep) sources.
A 100% non-porcine alternative, ideal for patients with religious, cultural, or dietary constraints.

**Clinically Validated**
Supported by robust preclinical and clinical evaluation.
Proven to be clinically equivalent to a well-established enoxaparin formulation, Ovinox delivers reliable anticoagulation with ethical sourcing.

**Therapeutically Versatile**
Broad-spectrum anticoagulant proven effective in both prevention and treatment of thromboembolic events.

**Globally Aligned**
Halal certified and compliant with ethical sourcing standards — supporting diverse healthcare systems and communities.

## HOW TO USE?

Available in 40mg/0.4ml | 60 mg/ 0.6 ml | 100mg/1.0 ml.

Pack contains two pre filled syringes.

Subcutaneous, Intravenous Route or arterial line of dialysis unit. Route depends on the indication the patient is being treated for.

**Prophylaxis of Venous Thromboembolism (VTE)**

General Surgery:
- 2,000IU (0.2mL) SC once daily for 7-10 days.
- The initial dose may be given several hours pre-operatively.

Orthopedic Surgery:
- 4,000 IU SC once daily, continued for 4–5 weeks.

Medically Ill Bedridden Patients:
- 4,000 IU SC once daily for a minimum of 6 days, up to 14 days.

**Treatment of Deep Vein Thrombosis (DVT) ± Pulmonary Embolism (PE)**
In uncomplicated patients with low risk of VTE recurrence: 150 IU/kg SC once daily for 10 days.
In patients such as those with obesity, with symptomatic PE, cancer or recurrent VTE: 100 IU/kg SC twice daily for 10 days.

**Acute Coronary Syndromes (ACS)**
Unstable Angina/NSTEMI:
- 100 IU/kg SC every 12 hours, with aspirin (acetylsalicylic acid)
- initial oral loading dose of 150–300 mg (in acetylsalicylic acid-naive patients) and a maintenance dose of 75–325 mg/day in long-term, regardless of treatment strategy.

Acute STEMI:
- Initial IV bolus: 3,000 IU
- Followed by: 100IU/kg SC every 12 hours
- Max dose for first 2 SC doses: 10,000 IU.
- Appropriate antiplatelet therapy, such as oral acetylsalicylic acid (75 mg to 325 mg once daily), should be administered concomitantly unless contraindicated.
- Continue for 8 days or until hospital discharge.
- Pre-PCI: If the last SC administration was given more than 8 hours before balloon inflation, an IV bolus of 30 IU/kg (0.3 mg/kg) enoxaparin sodium should be administered.

**Hemodialysis**
Standard Risk:
- 100 IU/kg added to arterial line at start of dialysis.

High Bleeding Risk:
- Double vascular access: 50 IU/kg
- Single vascular access: 75 IU/kg

# INSTRUCTION FOR USE

The pre-filled disposable syringe is ready for immediate use.

## SUB-CUTANEOUS INJECTION

- Disinfect site with alcohol swab and allow to dry.

- Administer in the supine position, preferably in the abdomen (alternating between left and right anterolateral/posterolateral areas).

- Do not expel air bubble from the syringe to avoid drug loss.
- The whole length of the needle should be introduced vertically (90°) into a skin fold held between the thumb and index finger.
- This skin fold should not be released until the injection is complete

- Do not massage post-injection.
- Discard syringe in sharps container.

## INTRAVENOUS INJECTION

- Ensure pre-filled syringe or diluted solution is prepared and verified.
- Use a dedicated IV access line (not shared with other drugs).
- Flush the line with normal saline (0.9%) or 5% dextrose before and after injection.
- Administer the IV bolus dose slowly through the IV line as instructed.
- Confirm full delivery of the dose—do not mix with any other medication.
- Dispose of the syringe and consumables in a sharps container.
- Monitor & manage the patient as per hospital protocol

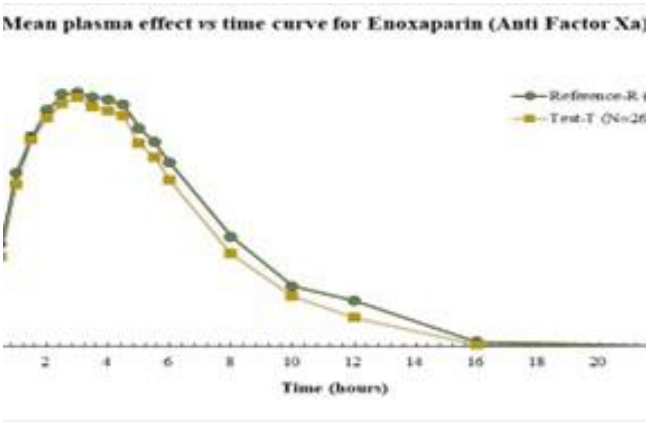
## ARTERIAL LINE USE

- It is administered through the arterial line of a dialysis circuit for the prevention of thrombus formation
- in the extra corporeal circulation during hemodialysis.
- Monitor patient closely for bleeding or hemodynamic changes as per hospital protocol.

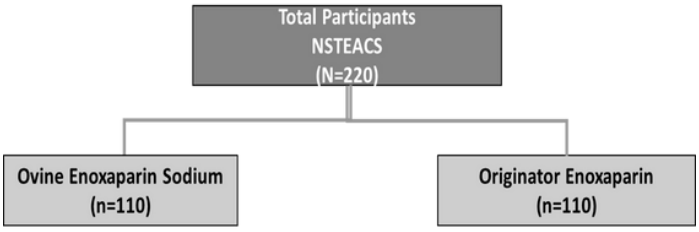
## CLINICAL & BIOEQUIVALENCE HIGHLIGHTS OF OVINOX

- **Bioequivalence Study**

  - Design: Randomized, open-label, 2-way crossover study (26 healthy volunteers; 7-day washout)
  - Comparators: Ovinox (0.4 mL) vs. Sanofi's Lovenox (0.4 mL)
  - Results: Demonstrated equivalent pharmacodynamic profiles (anti-Xa & anti-IIa activity) within 90% and 95% CI
  - Sites: Conducted in Indonesia and India




- **Clinical Study in NSTEACS Patients**




Primary Endpoint: Ovinox proven non-inferior to originator in reducing death and stroke

Secondary Outcomes: Comparable serious adverse event (SAE) profile & Higher MACE in ovine group, attributed to more critically ill baseline population

World's First Non-Porcine Enoxaparin

Over **5 Million doses** sold globally

Now Available in **UAE**

Meets **FDA Standards for Equivalence in**;

- Physicochemical Properties
- Oligosaccharide Sequence
- Biological and Biochemical Assays
- in vitro Immunogenicity Assays
- in vivo Pharmacodynamic Profile

100% Halal-certified, ovine-derived enoxaparin sodium

Backed by global safety data and clinical experience

Trusted by professionals across surgical, medical, and dialysis settings

## References


1. Bioequivalence Study of Ovinox™ and Originator Enoxaparin. Randomized, open-label, 2-way crossover trial in 26 healthy volunteers comparing PK/PD (anti-Xa/anti-IIa) profiles. Conducted in Indonesia and India. Data on file. Hepasonica Middle East, 2024.
2. NSTEMI Clinical Study. Comparative evaluation of Ovinox™ vs. originator enoxaparin in 220 patients with Non-ST-Elevation Acute Coronary Syndrome (NSTEACS). Data on file. PT Bio Farma, Indonesia
3. Halal Certification No. ARA-90150512-20906. Issued by ARA Halal Certification Services Center, confirming porcine-free manufacturing process of Ovinox™. Certificate on file. Hepasonica Middle East, 2024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