Noxarin

Enoxaparin

Description: Noxarin® is a low molecular weight heparin with a high anti-Xa activity and low anti-IIa or antithrombin activity.

Mode of Action: Noxarin® binds to and potentiates antithrombin (a circulating anticoagulant) to form a complex that irreversibly inactivates clotting factor Xa.

Pharmacokinetics: ***Absorption:*** Bioavailability (subcutaneous injection) ~ 100%. ***Distribution:*** Volume of distribution (anti-Factor Xa activity) = 4.3 liters. ***Metabolism:*** **Noxarin®** is metabolized in the liver into low molecular weight species by either or both desulfation and depolymerization. ***Elimination:*** A single dose of a subcutaneous injection of **Noxarin®** has an elimination half-life of 4.5 hours. Approximately 10–40% of the active and inactive fragments from a single dose are excreted by the kidneys. Dose adjustments based on kidney function are necessary in persons with reduced kidney function.

Composition: Noxarin® 20 mg pre-filled syringe injection: Each pre-filled syringe (0.2 ml) contains 2000 anti-Xa IU is equivalent to 20 mg enoxaparin sodium BP.
Noxarin® 40 mg pre-filled syringe injection: Each pre-filled syringe (0.4 ml) contains 4000 anti-Xa IU is equivalent to 40 mg enoxaparin sodium BP.
Noxarin® 60 mg pre-filled syringe injection: Each pre-filled syringe (0.6 ml) contains 6000 anti-Xa IU is equivalent to 60 mg enoxaparin sodium BP.
Noxarin® 80 mg pre-filled syringe injection: Each pre-filled syringe (0.8 ml) contains 8000 anti-Xa IU is equivalent to 80 mg enoxaparin sodium BP.

Indications: Noxarin® is a low molecular weight heparin (LMWH) indicated for: Prophylaxis of deep vein thrombosis (DVT) in abdominal surgery, hip replacement surgery, knee replacement surgery, or medical patients with severely restricted mobility during acute illness**,** Inpatient treatment of acute DVT with or without pulmonary embolism**,** Outpatient treatment of acute DVT without pulmonary embolism**,** Prophylaxis of ischemic complications of unstable angina and non–Q-wave myocardial infarction (MI)**,** Treatment of acute ST -segment elevation myocardial infarction (STEMI) managed medically or with subsequent percutaneous coronary intervention (PCI).

Dosage & Administration:

Indication	**Standard Regimen**
DVT prophylaxis in abdominal surgery	40 mg SC once daily up to 12 days
DVT prophylaxis in knee replacement surgery	30 mg SC every 12 hours up to 14 days
DVT prophylaxis in hip replacement surgery	30 mg SC every 12 hours or 40 mg SC once daily up to 14 days
DVT prophylaxis in medical patients	40 mg SC once daily up to 14 days
Inpatient treatment of acute DVT with or without pulmonary embolism	1 mg/kg SC every 12 hours or 1.5 mg/kg SC once daily (with warfarin) up to 17 days
Outpatient treatment of acute DVT without pulmonary embolism	1 mg/kg SC every 12 hours (with warfarin) up to 17 days
Unstable angina and non-Q-wave MI	1 mg/kg SC every 12 hours (with aspirin) 2 to 8 days
Acute STEMI in patients <75 years of age	30 mg single IV bolus plus a 1 mg/kg SC dose followed by 1 mg/kg SC every 12 hours at least 8 days (with aspirin)
Acute STEMI in patients ≥75 years of age	0.75 mg/kg SC every 12 hours (no bolus) at least 8 days (with aspirin)

Precautions: Noxarin® should be injected by deep subcutaneous route in prophylactic and curative treatment and by intravascular route during hemodialysis. Do not administer by the intramuscular route. **Noxarin®** should be used with caution in conditions with increased potential for bleeding, such as impaired hemostasis, history of peptic ulcer, recent ischemic stroke, uncontrolled severe arterial hypertension, diabetic retinopathy and recent neuro- or ophthalmologic surgery concomitant use of medications affecting hemostasis. It is recommended that the platelet counts be measured before the initiation of the treatment and regularly thereafter during treatment.

Contraindication: Noxarin® must not be used in the following situations:

- In patients with known hypersensitivity (allergy) to either **Noxarin®**, heparin or other low molecular weights heparins.
- In patients with active major bleeding and conditions with a high risk of uncontrolled hemorrhage including recent hemorrhagic stroke.

Use in Pregnancy & Lactation: ***Pregnancy:*** USFDA pregnancy category B. ***Lactation:*** It is not known whether **Noxarin®** is excreted in human milk.

Drug Interaction: It is recommended that agents which affect hemostasis should be discontinued prior to **Noxarin®** therapy unless strictly indicated. These agents include medications, such as: acetylsalicylic acid (and derivatives), NSAIDs (including ketorolac), ticlopidine, clopidogrel, dextran 40, glucocorticoids, thrombolytics and anticoagulants, other antiplatelet aggregation agents including glycoprotein IIb/IIa antagonists. If the combination is indicated, should be used with careful clinical and laboratory monitoring.

Storage: Store in a cool (Below 25˚ C temperature) and dry place protected from light.

Packaging:

Noxarin® 20 mg pre-filled syringe injection: Each box contains 1 pre-filled syringe (0.2 ml) containing 2000 anti-Xa IU is equivalent to 20 mg enoxaparin sodium BP in blister pack. ***Noxarin® 40 mg pre-filled syringe injection:*** Each box contains 1 pre-filled syringe (0.4 ml) containing 4000 anti-Xa IU is equivalent to 40 mg enoxaparin sodium BP in blister pack. ***Noxarin® 60 mg pre-filled syringe injection:*** Each box contains 1 pre-filled syringe (0.6 ml) containing 6000 anti-Xa IU is equivalent to 60 mg enoxaparin sodium BP in blister pack. ***Noxarin® mg pre-filled syringe injection:*** Each box contains 1 pre-filled syringe (0.8 ml) containing 8000 anti-Xa IU is equivalent to 80 mg enoxaparin sodium BP in blister pack.