Fondaparinux Sodium Injection

Product Name

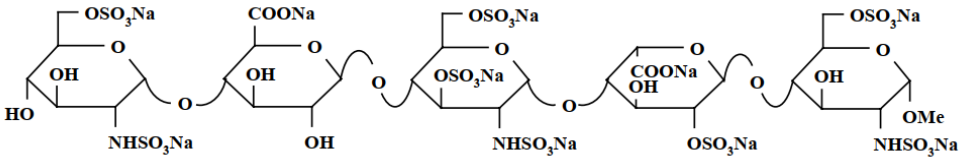
Generic name: Fondaparinux Sodium Injection

Ingredient

The active ingredient of this product is fondaparinux sodium.

Chemical name: methyl O-(2-deoxy-6-O-sulfo-2-sulfoamino-α-D-glucopyranosyl)-(1→4)-O-(β-D-glucopyranuronosyl)-(1→4)-O-(2-deoxy-3,6-di-Osulfo-2-sulfoamino-α-D-glucopyranosyl)-(1→4)-O-(2-O-sulfo-α-L-idopyranuronosyl)-(1→4)-2-deoxy-6-O-sulfo-2-sulfoamino- α-D-glucopyranoside, decasodium salt.

Chemical Structure:



Molecular formula: $C_{31}H_{43}N_3$ $Na_{10}O_{49}S_8$

Molecular weight: 1728.08

Excipients: sodium chloride, hydrochloric acid, sodium hydroxide, water for injection.

Description

This product is a prefilled glass syringe containing colourless to light yellow clear liquid.

Indication

Prevention of venous thromboembolic events (VTE) in adults undergoing major orthopaedic surgery of the lower limbs such as hip fracture, major knee surgery or hip replacement surgery.

Treatment of unstable angina or non-ST segment elevation myocardial infarction (UA/NSTEMI) in adults for whom urgent (< 120 mins) invasive management (PCI) is not indicated.

Treatment of ST segment elevation myocardial infarction (STEMI) in adults who are managed with thrombolytics or who initially are to receive no other form of reperfusion therapy.

Strength

0.5ml: 2.5mg

Dosage and administration

Patients undergoing major orthopaedic surgery

The recommended dose of fondaparinux sodium is 2.5 mg once daily administered subcutaneously after surgery.

The first dose should not be earlier than 6 hours after surgery and should only be administered after hemostasis has been established.

Treatment should be continued until the risk of venous thromboembolism has diminished, usually until the patient is up and about, at least 5 to 9 days after surgery. Experience has shown that in those undergoing hip fracture surgery, the risk of venous thromboembolism persists for more than 9 days after surgery. In these patients, the preventive use of fondaparinux sodium should be extended for an additional 24 days.

Treatment of unstable angina or non-ST segment elevation myocardial infarction (UA/NSTEMI)

The recommended dose of fondaparinux sodium is 2.5 mg once daily by subcutaneous injection. Treatment should be started as soon as possible after diagnosis and continued for up to 8 days or until discharge if less than 8 days.

If the patient will receive percutaneous coronary intervention (PCI), intraoperative unfractionated heparin should be used according to local clinical practice, taking into account the patient's potential risk of bleeding and the time from the last administration of fondaparinux sodium (See [precautions]). The timing of subsequent subcutaneous administration of fondaparinux sodium after sheath removal should be based on clinical judgment. In the major UA/NSTEMI clinical trials, fondaparinux sodium was not restarted earlier than 2 hours after sheath removal.

Treatment of ST segment elevation myocardial infarction (STEMI)

The recommended dose of fondaparinux sodium is 2.5 mg once daily. The first dose of fondaparinux sodium should be administered intravenously, followed by subcutaneous injection. Treatment should be administered as soon as possible after the diagnosis is established, and treatment should be continued for up to 8 days or until discharge if less than 8 days.

If the patient will receive non-primary PCI, intraoperative unfractionated heparin should be used according to local clinical practice, taking into account the patient's potential risk of bleeding and the time from the last administration of fondaparinux sodium (See [precautions]). The timing of subsequent subcutaneous administration of fondaparinux sodium after sheath removal should be based on clinical judgment. In the major STEMI clinical trials, fondaparinux sodium was not restarted earlier than 3 hours after sheath removal.

In patients with ST-segment elevation myocardial infarction or unstable angina/non-ST-segment elevation myocardial infarction, in those who will receive coronary artery bypass grafting (CABG), if possible, fondaparinux sodium should not be given within 24 hours prior to surgery and can be restarted 48 hours after surgery.