# Fonidel™ 2.5

## Fondaparinux Sodium USP 2.5 mg

**PRESENTATION**

**Fonidel**™ 2.5 Pre-filled syringe (PFS) Injection: Each Pre-filled syringe (0.5 ml) contains Fondaparinux Sodium USP 2.5 mg.

**PHARMACOLOGY**

The antithrombotic activity of **Fonidel**™ (Fondaparinux Sodium) is the result of selective inhibition of Factor Xa. By selectively binding to antithrombin III (ATIII), Fondaparinux Sodium potentiates (about 300 times) the innate neutralization of Factor Xa by ATIII. Neutralization of Factor Xa interrupts the blood coagulation cascade and thus inhibits thrombin formation and thrombus development.

Fondaparinux Sodium does not inactivate thrombin (activated Factor II) and has no known effect on platelet function. At the recommended dose, Fondaparinux Sodium does not affect fibrinolytic activity or bleeding time.

**INDICATIONS**

**Fonidel**™ (Fondaparinux Sodium) is a Factor Xa inhibitor (anticoagulant) indicated for:

- Prophylaxis of deep vein thrombosis (DVT) in patients undergoing hip fracture surgery (including extended prophylaxis), hip replacement surgery, knee replacement surgery or abdominal surgery
- Treatment of DVT or acute pulmonary embolism (PE) when administered in conjunction with warfarin

**DOSAGE & ADMINISTRATION**

*Prophylaxis of deep vein thrombosis:* Fondaparinux Sodium 2.5 mg subcutaneously **once daily** after hemostasis has been established. The initial dose should be given no earlier than 6 to 8 hours after surgery and continued for 5 to 9 days. For patients undergoing hip fracture surgery, extended prophylaxis up to 24 additional days is recommended.

*Treatment of deep vein thrombosis and pulmonary embolism:* Fondaparinux Sodium 5 mg (body weight <50 kg), 7.5 mg (50 to 100 kg) or 10 mg (>100 kg) subcutaneously **once daily**. Treatment should continue for at least 5 days until INR 2 to 3 achieved with warfarin sodium.

**CONTRAINDICATIONS**

Fondaparinux Sodium is contraindicated in the following conditions:

- Severe renal impairment (creatinine clearance [CrCl] <30 mL/min)
- Active major bleeding
- Bacterial endocarditis
- Thrombocytopenia
- Body weight <50 kg (venous thromboembolism [VTE] prophylaxis only)
- History of serious hypersensitivity reaction to Fondaparinux Sodium

**PRECAUTIONS**

- Use with caution in patients who have conditions or are taking concomitant medications that increase risk of hemorrhage
- Bleeding risk is increased in renal impairment and in patients with low body weight <50 kg
- Consider the potential risks and benefits before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis
- Thrombocytopenia can occur with administration of Fondaparinux Sodium
- Periodic routine complete blood counts (including platelet counts), serum creatinine level and stool occult blood tests are recommended

**ADVERSE REACTIONS**

The most common adverse reactions associated with the use of Fondaparinux Sodium are- bleeding complications, mild local irritation (injection site bleeding, rash and pruritus) following subcutaneous injection, anemia, insomnia, hypokalemia, dizziness, hypotension, confusion, bullous eruption, hematoma & post-operative hemorrhage.

**DRUG INTERACTIONS**

Discontinue agents that may enhance the risk of hemorrhage prior to initiation of therapy with Fondaparinux Sodium unless essential. If co-administration is necessary, monitor patients closely for hemorrhage.

**USE IN SPECIAL POPULATION**

*Use in Pregnancy:* Pregnancy Category: B

*Use in Lactation:* It is not known whether Fondaparinux sodium is excreted in human milk. Caution should be exercised when Fondaparinux Sodium is administered to a nursing woman.

*Pediatric Use:* Safety and effectiveness of Fondaparinux Sodium in pediatric patients have not been established.

*Geriatric Use:* In clinical trials, the efficacy of Fondaparinux Sodium in the elderly (65 years or older) was similar to that seen in patients younger than 65 years; however, serious adverse events increased with age.

*Use in renal or hepatic impairment:* The risk of bleeding is increased with reduced renal or hepatic function.

**STORAGE**

Store below 25°C. Do not freeze. Keep the medicine out of reach of children.

**HOW SUPPLIED**

**Fonidel**™ 2.5: Each box contains 1 pre-filled syringe (containing 2.5 mg Fondaparinux Sodium USP) in blister pack.

*Manufactured by*

**SQUARE PHARMACEUTICALS LTD.**

Kaliakoir, Gazipur, Bangladesh

TM - Trade Mark

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