

AFOGATRAN

**For the use of a Cardiologist, Orthopaedic Surgeon, Neurologist, Intensive Care Specialist,
Surgeon and Haematologist only**

Abbreviated Prescribing information for **AFOGATRAN** [(Dabigatran Etexilate Mesilate Capsules 75 mg/110 mg/150 mg) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Dabigatran etexilate is a small molecule prodrug which is rapidly absorbed and converted to dabigatran by esterase-catalysed hydrolysis in plasma and in the liver. Dabigatran is a potent, competitive, reversible direct thrombin inhibitor and is the main active principle in plasma. Dabigatran also inhibits free thrombin, fibrin-bound thrombin and thrombin-induced platelet aggregation

INDICATION: Prevention of stroke, systemic embolism and reduction of vascular mortality in adult patients with atrial fibrillation and venous thromboembolic events in patients who have undergone orthopaedic surgery.

DOSAGE AND ADMINISTRATION: The recommended daily dose of dabigatran is 300 mg and 220 mg depending on the condition to be treated.

CONTRAINDICATION: It is contraindicated in patients with severe renal impairment, active clinically significant bleeding, Concomitant treatment with any other anticoagulants, Hepatic impairment or liver disease expected to have any impact on survival, Concomitant treatment with systemic ketoconazole, cyclosporine, itraconazole and dronedarone, Prosthetic heart valves requiring anticoagulant treatment.

WARNINGS & PRECAUTIONS: It should be used with caution in conditions with an increased risk of bleeding and in situations with concomitant use of drugs affecting haemostasis by inhibition of platelet aggregation.

DRUG INTERACTIONS: It may interact with Anticoagulants and antiplatelet aggregation medicinal products, P-gp inhibitors, P-gp inducers, P-gp substrates and pantoprazole.

ADVERSE REACTIONS: Anemia, Epistaxis, Gastrointestinal haemorrhage, Abdominal pain, Diarrhoea, Dyspepsia, Nausea, Skin haemorrhage and Genitourological haemorrhage, including haematuria.

MARKETED BY:



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(Additional information is available on request)