Information For the User Dabigatran 75 mg Tablet

Dabgiv 75 Tablet

Brand Name: Dabgiv 75 Tablet

Composition:

Each capsule contains:

Dabigatran Etexilate Mesylate IP equivalent to Dabigatran 75 mg

Therapeutic Indication:

Indicated for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation

Used for the treatment and prevention of deep vein thrombosis (DVT) and pulmonary embolism (PE)

Helps in reducing the risk of thromboembolic events after orthopedic surgeries such as hip or knee replacement

Mechanism of Action:

Dabigatran is a direct thrombin (Factor IIa) inhibitor

It prevents the conversion of fibrinogen to fibrin, thereby inhibiting clot formation Provides anticoagulation effect without the need for routine monitoring in most patients

Dosage & Administration:

Usual adult dose: 75 mg to 150 mg twice daily depending on indication and renal function

Take orally with a full glass of water

Can be taken with or without food

Dose adjustments are required in renal impairment or in elderly patients

Contraindications:

Hypersensitivity to Dabigatran or any component of the formulation Active clinically significant bleeding Severe renal impairment (creatinine clearance <15 mL/min) Pregnancy and lactation

Warnings & Precautions:

Use with caution in patients at increased risk of bleeding or with renal dysfunction Avoid concomitant use with other anticoagulants unless specifically indicated Discontinue before surgical procedures as advised by the physician Monitor for signs of bleeding and hemoglobin levels

Side Effects:

Common: bleeding, bruising, gastrointestinal discomfort, dyspepsia

Less common: anemia, nausea, diarrhea Rare: severe hemorrhage, allergic reactions

Storage:

Store in a cool, dry, and dark place below 25°C

Protect from moisture and light Keep out of reach of children

Packaging:

Dabgiv 75 Tablet is available in blister or alu-alu strip packs

Schedule:

Schedule H Prescription Drug – To be sold by retail on the prescription of a registered medical practitioner only

Manufactured in India for:



(An ISO 9001: 2015 Certified Co.) Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113

TM: Trademark Applied for