

PRESS RELEASE

23rd November, 2021, Vadodara, India

Alembic Pharmaceuticals announces USFDA Tentative Approval for Dabigatran Etexilate Capsules, 150 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Dabigatran Etexilate Capsules, 150 mg. The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) PRADAXA® Dabigatran Etexilate Mesylate Capsules, Eq to 150 mg base, Boehringer Ingelheim. Dabigatran Etexilate Capsules are indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, and for the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients who have been treated with a parenteral anticoagulant for 5 to 10 days. It is also indicated to reduce the risk of recurrence of DVT and PE in patients who have been previously treated.

Dabigatran Etexilate Capsules, 150 mg have an estimated market size of US\$ 410 million for twelve months ending Sep. 2021 according to IQVIA.

Alembic has received year to date (YTD) 14 approvals (11 final approvals and 3 tentative approvals) and a cumulative total of 153 ANDA approvals (134 final approvals and 19 tentative approvals) from USFDA, including this first inhalational ANDA approval.

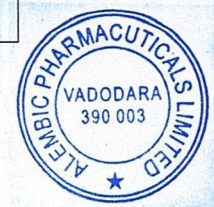
About Alembic Pharmaceuticals Limited

Alembic Pharmaceuticals Limited, a vertically integrated research and development pharmaceutical company, has been at the forefront of healthcare since 1907. Headquartered in India, Alembic is a publicly listed company that manufactures and markets generic pharmaceutical products all over the world. Alembic's state of the art research and manufacturing facilities are approved by regulatory authorities of many developed countries including the USFDA. Alembic is one of the leaders in branded generics in India. Alembic's brands, marketed through a marketing team of over 5000 are well recognized by doctors and patients.

Information about Alembic can be found at <http://www.alembicpharmaceuticals.com/>; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

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