

Alembic Pharmaceuticals gets USFDA nod for Dabigatran Etexilate Capsules used to reduce risk of stroke

Summary

Alembic Pharmaceuticals said the approved ANDA is therapeutically equivalent to the reference listed drug product Pradaxa Capsules, 75 mg, 110 mg, and 150 mg of Boehringer Ingelheim Pharmaceuticals, Inc. Dabigatran Etexilate Capsules 75 mg and 150 mg have an estimated market size of \$179 million for twelve months ending in March 2024, according to IQVIA.



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[Alembic Pharmaceuticals](#) on Tuesday announced it has received final approval from the US Food and Drug Administration (USFDA) for its abbreviated new drug application (ANDA) for Dabigatran Etexilate Capsules, 75 mg and 150 mg. The firm also received tentative approval for Dabigatran Etexilate Capsules, 110 mg. Shares of the firm were down over 2% on Tuesday.

Alembic Pharmaceuticals said the approved ANDA is therapeutically equivalent to the reference listed drug product Pradaxa Capsules, 75 mg, 110 mg, and 150 mg of Boehringer Ingelheim Pharmaceuticals, Inc.

Dabigatran Etexilate Capsules 75 mg and 150 mg have an estimated market size of \$179 million for twelve months ending in March 2024, according to IQVIA. At the same time, Dabigatran Etexilate Capsules 110 mg have an estimated market size of \$5 million.

The drug is indicated for the reduction of risk of stroke and systemic embolism in non-valvular atrial fibrillation in adult patients as well as treatment and reduction in the risk of recurrence of deep venous thrombosis and pulmonary embolism in adult patients.

Alembic has a cumulative total of 205 ANDA approvals from USFDA.

Recently, the firm announced it has received final approval from the USFDA for its ANDA for Icatibant Injection, 30 mg/3 mL (10 mg/mL) single-dose prefilled syringe. This is the first peptide product approval from the USFDA received by the company, it said.

During the fourth quarter of fiscal year 2024, the company announced a 175 rise in its net profit at ₹ 178 crore. Net sales rose 8% during the quarter to ₹1,517 crore. Earnings before interest, tax, depreciation, and amortisation (EBITDA) rose 29% to ₹263 crore. For the full fiscal year 2024, net profit rose 80% to ₹616 crore while net sales increased 10% to ₹6,229 crore. EBITDA rose 41% to ₹961 crore.

Shares of the company have gained over 13% since the beginning of the year. The stock has risen over 42% in the last one year.

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