

PRESS RELEASE

26th February, 2026 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Lamotrigine Orally Disintegrating Tablets USP, 25 mg, 50 mg, 100 mg and 200 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Lamotrigine Orally Disintegrating Tablets USP, 25 mg, 50 mg, 100 mg and 200 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Lamictal ODT Orally Disintegrating Tablets, 25 mg, 50 mg, 100 mg, and 200 mg, of GlaxoSmithKline LLC.

Lamotrigine is indicated as adjunctive therapy in patients aged 2 years and older for: i) partial-onset seizures, ii) primary generalized tonic-clonic (PGTC) seizures, and iii) generalized seizures of Lennox-Gastaut syndrome. It is also indicated for conversion to monotherapy in adults (aged 16 years and older) with partial-onset seizures who are receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as the single antiepileptic drug (AED). Lamotrigine is indicated for the maintenance treatment of bipolar I disorder to delay the time to occurrence of mood episodes in patients treated for acute mood episodes with standard therapy. Refer label for a detailed indication.

Lamotrigine Orally Disintegrating Tablets USP, 25 mg, 50 mg, 100 mg and 200 mg, have an estimated market size of US\$ 27 million for twelve months ending December 2025 according to IQVIA.

Alembic has a cumulative total of 235 ANDA approvals (216 final approvals and 19 tentative approvals) from USFDA.

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 field force of over 5500 are well recognized by doctors and patients.

Information about the Company can be found at www.alembicpharmaceuticals.com; (Reuters:ALEM.NS) (Bloomberg:ALPM) (NSE:APLLTD) (BSE:533573)

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