

PRESS RELEASE

16th April, 2026 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Methotrexate Injection USP, 50 mg/2 mL (25 mg/mL) Multi-Dose Vials & 1g/40 mL (25 mg/mL) Single-Dose Vials.

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) Methotrexate Injection USP, 50 mg/2 mL (25 mg/mL) Multi-Dose Vials & 1g/40 mL (25 mg/mL) Single-Dose Vials. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Methotrexate Injection USP, 50 mg/2 mL (25 mg/mL) Multi-Dose Vials & 1g/40 mL (25 mg/mL) Single-Dose Vials, of Hospira, Inc. Methotrexate Injection is a folate analog metabolic inhibitor indicated for neoplastic diseases: i) Acute Lymphoblastic Leukemia, ii) Meningeal Leukemia: Prophylaxis and Treatment, iii) Non-Hodgkin Lymphoma, iv) Osteosarcoma, v) Breast Cancer, vi) Squamous Cell Carcinoma of the Head and Neck, and vii) Gestational Trophoblastic Neoplasia. It is also indicated for the treatment of: i) rheumatoid arthritis (RA), ii) polyarticular juvenile idiopathic arthritis (pJIA), and iii) severe psoriasis. Refer label for a detailed indication.

Alembic has a cumulative total of 236 ANDA approvals (218 final approvals and 18 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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