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Alembic Pharmaceuticals receives USFDA approval for Febuxostat tablets

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Alembic Pharmaceuticals Limited has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Febuxostat Tablets, 40 mg and 80 mg. The approved ANDA is therapeutically equivalent to the: reference listed drug (RLD), Uloric Tablets, 40 mg and 80 mg, of Takeda Pharmaceuticals U.S.A., Inc. (Takeda).

Febuxostat Tablets are xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in adult patients with gout who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable. Febuxostat Tablets are not recommended for the treatment of asymptomatic hyperuricemia.

Febuxostat Tablets have an estimated market size of US$ 578 million for twelve months ending December 2018 according to IQVIA. Alembic had previously received tentative approval for this ANDA.