

## Alembic Pharmaceuticals receives FDA approval for Midodrine Hydrochloride tablets

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The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), ProAmatine tablets, 2.5 mg, 5 mg, and 10 mg, of Takeda Pharmaceuticals US, Inc. Midodrine hydrochloride tablets are indicated for the treatment of symptomatic orthostatic hypotension (OH),



Alembic Pharmaceuticals Limited announced it has received approval from the US Food & Drug Administration (US FDA) for its abbreviated new drug application (ANDA) Midodrine Hydrochloride tablets USP, 2.5 mg, 5 mg, and 10 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), ProAmatine tablets, 2.5 mg, 5 mg, and 10 mg, of Takeda Pharmaceuticals US, Inc. Midodrine hydrochloride tablets are indicated for the treatment of symptomatic orthostatic hypotension (OH).

Midodrine Hydrochloride tablets USP 2.5 mg, 5 mg, and 10 mg have an estimated market size of \$60 million for twelve months ending September 2020 according to IQVIA.