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Alembic Pharmaceuticals receives FDA approval for Midodrine Hydrochloride tablets

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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.