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ASIA EDITION

Alembic Pharma gets USFDA nod for Clonazepam to treat seizures

July 2, 2019 | News

Clonazepam orally disintegrating tablet is useful alone or as an adjunct in the treatment of the Lennox-Gastaut syndrome (petit mal variant), akinetic and myoclonic seizures



Alembic Pharmaceuticals Limited has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Clonazepam Orally Disintegrating Tablets USP, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg and 2 mg.

The approved ANDA is therapeutically equivalent to the reference listed drug (RLD), Klonopin Orally Disintegrating Tablets, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg and 2 mg, of Hoffmann-La Roche, Inc. (Roche). Clonazepam orally disintegrating tablet is useful alone or as an adjunct in the treatment of the Lennox-Gastaut syndrome (petit mal variant), akinetic and myoclonic seizures.

In patients with absence seizures (petit mal) who have failed to respond to succinimides, clonazepam orally disintegrating tablets may be useful. It is also indicated for the treatment of panic disorder, with or without agoraphobia, as defined in DSMV.

Clonazepam Orally Disintegrating Tablets USP has an estimated market size of US$ 20 million for twelve months ending December 2018 according to IQVIA. Alembic now has a total of 98 ANDA approvals (86 final approvals and 12 tentative approvals) from USFDA.