

Alembic Pharma gets USFDA approval for generic Clobex spray

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Clobetasol Propionate Spray, 0.05% is indicated for the treatment of moderate to severe plaque psoriasis



Alembic Pharmaceuticals Limited, a vertically integrated research and development pharmaceutical company, announces its joint venture Aleor Dermaceuticals receives Approval from US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Clobetasol Propionate Spray, 0.05%.

The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Clobex® Spray, 0.05% of Galderma Laboratories L.P. (Galderma). Clobetasol Propionate Spray, 0.05% is indicated for the treatment of moderate to severe plaque psoriasis affecting up to 20% body surface area (BSA) in patients 18 years of age or older.

Clobetasol Propionate Spray, 0.05%, has an estimated market size of US\$ 22 million for twelve months ending December 2018 according to IQVIA. Alembic has a cumulative total of 103 ANDA approvals (91 final approvals and 12 tentative approvals) from USFDA.