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Alembic’s JV Aleor gets USFDA nod for Diclofenac Sodium Solution

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Diclofenac Sodium Topical Solution USP, 2% w/w is indicated for the treatment of the pain of osteoarthritis of the knee(s)

Alembic Pharmaceuticals Limited (Alembic), a vertically integrated research and development pharmaceutical company, headquartered in India, manufactures and markets generic pharmaceutical products all over the world.

Alembic has announced that its joint venture Aleor Dermaceuticals Limited (Aleor) has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Diclofenac Sodium Topical Solution USP, 2% w/w.

The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Pennsaid Topical Solution, 2% w/w, of HZNP Medicines LLC (HZNP). Diclofenac Sodium Topical Solution USP, 2% w/w is indicated for the treatment of the pain of osteoarthritis of the knee(s).

Diclofenac Sodium Topical Solution USP, 2% w/w, has an estimated market size of US$ 974 million for twelve months ending December 2018 according to IQVIA.

Alembic has a cumulative total of 109 ANDA approvals (96 final approvals and 13 tentative approvals) from USFDA.

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