

Strides gets USFDA tentative nod for pain relieving drug

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Strides Pharma Science Limited (Strides) has announced that its step-down wholly owned subsidiary, Strides Pharma Global Pte. Limited, Singapore, has received tentative approval for Diclofenac Potassium Softgel Capsules, 25 mg from the United States Food & Drug Administration (USFDA).

The product is a generic version of Zipsor Capsules, 25 mg, of Assertio Therapeutics, Inc. Strides specializes in softgel domain and is a global leader in the Rx space. Strides now has a large portfolio of softgel products which comprises of 11 approved products for the US markets along with a strong product pipeline cutting across several therapeutic segments.

Diclofenac Potassium Softgel Capsules is part of Strides niche and small volume product portfolio with limited competition in the US market.

According to IQVIA MAT data, the US market for Diclofenac Potassium Softgel Capsules, 25 mg is approximately US\$ 30 Mn. Strides can launch the product earliest by September 2022 based on terms of settlement.

On receiving full approval, the product will be manufactured at the company's Oral dosage facility at Bangalore and marketed by Strides Pharma Inc in the US Market.

The company has 102 cumulative ANDA filings with USFDA of which 67 ANDAs have been approved and 35 are pending approval. About Diclofenac Potassium Softgel Capsules Diclofenac Potassium Softgel Capsule is a nonsteroidal anti-inflammatory drug used to relieve pain and swelling from various mild to moderate painful conditions. It is used to treat muscle aches, backaches, dental pain, menstrual cramps, and sports injuries.