Strides Shasun Limited
(Formerly Strides Arcolab Limited)
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Strides Shasun receives USFDA Approval
For Ibuprofen Softgel OTC Capsules

Approval strengthens Strides global Ibuprofen portfolio
Product to be commercialized in Q4 FY 19

Bangalore, April 2, 2018 Strides Shasun Limited today announced that it’s wholly owned subsidiary Strides Pharma Global Pte. Limited has received approval for Ibuprofen Capsules, 200 mg OTC from the United States Food & Drug Administration (US FDA). This is a pre-GDUFA file for the company and the approval has come through after a long approval cycle of almost 6 years. The approval further strengthens Strides global ibuprofen portfolio that now includes multiple products in oral dosage format.

Ibuprofen Capsules is generic version of Advil Liqui-Gels, 200 mg, of Pfizer Inc. According to IRi data, the US OTC market for Ibuprofen Capsules is approximately USD 300 Million including an attractive private label market of US$ 60 Million.

The recent supply chain disruptions have led to a significant shortage for Ibuprofen API globally. With a focus to secure its API supply chain for the product, the company under prior approval supplements (PASs) filing will apply for a source change to Solara Active Pharma Sciences, a group company having a leading API franchise. The product will be commercialized in Q4 FY 19 post completion of API source change process. The company expects to garner 20% of the private label market share. The product will be manufactured at the company’s oral dosage facility at Bangalore.

The company has 74 cumulative ANDA filings with USFDA of which 45 ANDAs have been approved as of date and 29 are pending approval.
**About Ibuprofen Capsules**

Ibuprofen is used to relieve pain from various conditions such as headache, dental pain, muscle aches, or arthritis. It is also used to reduce fever and to relieve minor aches and pain due to the common cold or flu. Ibuprofen is a nonsteroidal anti-inflammatory drug (NSAID)

**About Strides Shasun**

Strides Shasun, listed on the BSE Limited (532531) and National Stock Exchange of India Limited (STAR), is a vertically integrated global pharmaceutical Company headquartered in Bangalore. The Company has two business verticals, viz., Regulated Markets and Emerging Markets.

The Company has global manufacturing footprint with 7 manufacturing facilities spread across three continents including 5 US FDA approved facilities and 2 facilities for the emerging markets. The Company has two dedicated R&D facilities in India with global filing capabilities and a strong commercial footprint across 100 countries. Additional information is available at the Company’s website at [www.stridesarco.com](http://www.stridesarco.com)

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