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FDA approves Lupin's Empagliflozin, Metformin Hydrochloride ER tablets

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Empagliflozin and Metformin Hydrochloride Extended-Release (ER) Tablets, 5 mg/1000 mg, 10 mg/1000 mg, 12.5 mg/1000 mg, and 25 mg/1000 mg, are indicated as an adjunct to diet and exercise, to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and metformin hydrochloride is appropriate

Lupin Limited, a global pharmaceutical company, announced that it has received tentative approval for its Empagliflozin and Metformin Hydrochloride Extended-Release (ER) tablets, 5 mg/1000 mg, 10 mg/1000 mg, 12.5 mg/1000 mg, and 25 mg/1000 mg, from the United States Food and Drug Administration, to market a generic equivalent of Synjardy® XR tablets, 5 mg/1000 mg, 10 mg/1000 mg, 12.5 mg/1000 mg, and 25 mg/1000 mg, of Boehringer Ingelheim Pharmaceuticals, Inc. The product will be manufactured at Lupin’s Nagpur facility in India.

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Empagliflozin and Metformin Hydrochloride ER Tablets (RLD: Synjardy®XR) had estimated annual sales of $357 million in the US (IQVIA MAT November 2020).