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FDA nod for Lupin's generic drug

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Pharma Major Lupin has received final approval for its potassium chloride extended release Capsules USP, 8 mEq and 10 mEq from the United States Food and Drug Administration (US FDA). Lupin's US subsidiary shall commence promoting the product in the US shortly.

Lupin's capsules USP, 8 mEq and 10 mEq, are the AB rated generic equivalent of Actavis Labs potassium chloride extended release capsules USP, 8 mEq and 10 mEq.

It is indicated for the treatment of patients with hypokalemia, with or without metabolic alkalosis, in digitalis intoxications and in patients with hypokalemic familial periodic paralysis. It is also indicated for the prevention of hypokalemia in patients who would be at a particular risk.

Potassium chloride extended release capsules had US sales of $85.6 million (IMS MAT September 2015).