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USFDA nod for Aurobindo Pharma

15 June 2017 | News

Sevelamer Carbonate oral suspension is used for controlling serum phosphorus in patients with chronic kidney disease on dialysis.

Drug firm Aurobindo Pharma has received final approval from the US Food and Drug Administration (USFDA) to make oral suspension used for controlling serum phosphorus in patients with chronic kidney disease on dialysis.

Sevelamer Carbonate oral suspension will be manufactured in 0.8 gm and 2.4 gm quantities. The company's drug is a therapeutic equivalent generic version of Genzyme's Renvela oral suspension. According to IMS April 2017 data, the approved product has an estimated market size of USD 140 million. Renvela is indicated for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis.

Renvela contains sevelamer, a non-absorbed phosphate binding crosslinked polymer, free of metal and calcium. Since sevelamer binds bile acids, it may interfere with the absorption of fat soluble vitamins such as A, D, E and K.

This is the 116th ANDA (including 19 tentative approvals) to be approved out of Unit VII formulation facility in Hyderabad, India used for manufacturing oral products for Aurobindo Pharma.