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Lupin receives USFDA approval for Ethacrynic Acid Tablets USP

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Lupin's Ethacrynic Acid Tablets USP, 25 mg, is the generic version of Edecrin® Tablets, 25 mg, of Bausch Health Americas, Inc.

Indian Pharma major Lupin Limited (Lupin) on 9 Sep 2019, announced that it has received approval for its Ethacrynic Acid Tablets USP, 25 mg, from the United States Food and Drug Administration (U.S. FDA).

Lupin's Ethacrynic Acid Tablets USP, 25 mg, is the generic version of Edecrin® Tablets, 25 mg, of Bausch Health Americas, Inc. It is indicated for treatment of edema when an agent with greater diuretic potential than those commonly employed is required.

- Treatment of the edema associated with congestive heart failure, cirrhosis of the liver, and renal disease, including the nephrotic syndrome.
- Short-term management of ascites due to malignancy, idiopathic edema, and lymphedema.
- Short-term management of hospitalized pediatric patients, other than infants, with congenital heart disease or the nephrotic syndrome.
- Intravenous ethacrynic acid sodium is indicated when a rapid onset of diuresis is desired, e.g., in acute pulmonary edema, or when gastrointestinal absorption is impaired or oral medication is not practicable.

Ethacrynic Acid Tablets USP had annual sales of approximately USD 24 million in the US (IQVIA MAT June 2019).