

Lupin receives tentative USFDA approval for Mirabegron ER Tablets

28 June 2019 | News

It is a generic version of Myrbetriq Extended Release Tablets, 25 mg and 50 mg, of Astellas Pharma



Lupin has announced that it has received tentative approval for its Mirabegron Extended Release (ER) Tablets, 25 mg and 50 mg, from the United States Food and Drug Administration (FDA), to market a generic version of Myrbetriq Extended Release Tablets, 25 mg and 50 mg, of Astellas Pharma Global Development Inc. (Astellas).

Lupin's Mirabegron ER Tablets, 25 mg and 50 mg, is a generic version of Myrbetriq Extended Release Tablets, 25 mg and 50 mg, of Astellas.

It is indicated for the treatment of Overactive Bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.

Mirabegron ER Tablets 25 mg and 50 mg had annual sales of approximately USD 1501.6 mn in the US (IMS MAT March 2019).