

Zydus Cadila announces final USFDA approval for Macitentan Tablets, 10 mg and gets eligibility for 180-day shared exclusivity

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Zydus Cadila has received final approval from the USFDA to market Macitentan Tablets, 10 mg (US RLD: Opsumit Tablets). Macitentan is used to manage the symptoms of pulmonary arterial hypertension. Macitentan is in a class of medications called endothelin receptor antagonists. It works by stopping the action of endothelin, a natural substance that causes blood vessels to narrow and prevents normal blood flow in people who have Pulmonary Arterial Hypertension.

According to the USFDA letter, Zydus was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Macitentan Tablets, 10 mg. Therefore, with this approval, Zydus is eligible for 180 days of shared generic drug exclusivity for Macitentan Tablets, 10 mg.

The group now has 314 approvals and has so far filed over 400 ANDAs since the commencement of the filing process in FY 2003-04.

About Zydus

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs nearly 25000 people worldwide and is dedicated to creating healthier communities globally.

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