Generic Name:
Mirabegron
Trade Name:
Myrbetriq
Company:
Astellas
Notes:

FDA announced the approval of mirabegron for the management of overactive bladder (OAB) in adults. This is the first OAB treatment that has a novel mechanism of action in that it enhances urine storage by stimulating beta-3 adrenoceptors in the bladder.

Approval was based on data from three double-blind, placebo-controlled, multicenter clinical trials involving 4,116 patients with OAB who were randomly assigned to take mirabegron at doses of 25, 50, or 100 mg, or placebo once daily for 12 weeks. According to data from these trials, patients given mirabegron 25 or 50 mg had a reduced number of urinations and wetting accidents in a 24-hour period. In addition, patients treated with the 50-mg dose expelled a greater amount of urine, demonstrating the drug?s effectiveness in improving the storage capacity of the bladder.

The most common adverse events with mirabegron included elevations in blood pressure, nasopharyngitis, urinary tract infection, constipation, fatigue, tachycardia, and abdominal pain. The drug is not recommended for use in patients with severe uncontrolled high blood pressure, end-stage kidney disease, or severe liver impairment.

Medication Monitor Categories:
New Drug Approvals
Use:

Management of OAB in adults