# FDA approves Myrbetriq for use in children with neurogenic detrusor overactivity

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Myrbetriq (mirabegron extended-release tablets) is now approved for

treatment of neurogenic detrusor overactivity, common in patients with spina bifida, in children 3 years and older, the U.S. Food and Drug Administration announced yesterday.

The expanded indication approval also applied to Myrbetriq Granules (mirabegron for extended-release oral suspension), which are intended for children who may have difficulty swallowing tablets. The drug is also indicated for treatment of overactive bladder in adults.

Approval of Myrbetriq for this indication was based on a phase 3 study of 86 patients ages 3 to 17 years. After 24 weeks of treatment with Myrbetriq, researchers found patients improved in maximum cystometric capacity, number of detrusor contractions, volume of urine held until the first detrusor contraction, and the number of daily urine leakage episodes.

The most commonly reported side effects included urinary tract infection, nasopharyngitis, constipation, and headache. The FDA notes that when taking Myrbetriq, patients may experience angioedema, increased blood pressure, and worsening of blood pressure for those with a history of high blood pressure.

The approval was granted to Astellas Pharma US Inc. The company says Myrbetriq tablets are currently available in the United States, while Myrbetriq Granules will be available in the United States by the end of this year.

**More information:** More Information



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