# VESIcare LS approved for neurogenic detrusor overactivity

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VESIcare LS (solifenacin succinate) oral suspension is now approved to treat neurogenic detrusor overactivity (NDO) in children 2 years and older, the U.S. Food and Drug Administration announced Tuesday.

VESIcare (solifenacin succinate) tablets were approved in 2004 to treat overactive bladder in patients 18 years and older. VESIcare LS is the first FDA-approved treatment for NDO in patients as young as 2 years and requires only once-daily dosing as opposed to the current standard treatment, which requires dosing up to three times a day, according to Christine P. Nguyen, M.D., acting director of the FDA Division of Urology, Obstetrics and Gynecology in the Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine in the Center for Drug Evaluation and Research.

The approval of VESIcare LS was based on data from two clinical trials, including one with 17 patients ages 2 to less than 5 years old and one with 49 patients ages 5 to 17 years old. After 24 weeks of treatment, patients in each study could hold an average of 39 and 57 mL more urine, respectively, than they could hold at baseline. In both studies, researchers also observed reductions in spontaneous bladder contractions, bladder pressure, and number of incontinence episodes.

The most commonly reported side effects of VESIcare LS were constipation, dry mouth, and urinary tract infection. Somnolence and severe allergic reactions such as angioedema and anaphylaxis have also been reported in the past with the active ingredient solifenacin succinate. The FDA notes that health care professionals should ensure they do not exceed the recommended starting dose of VESIcare LS in patients who are also taking CYP3A4 inhibitors. VESIcare LS is contraindicated in patients with severe liver failure, clinically significant bladder outlet obstruction in absence of clean intermittent catheterization, or decreased gastrointestinal motility and those at high risk for QT prolongation.

Approval was granted to Astellas Pharma.

**More information:** More Information