

Tektura® (aliskiren) – Expanded indication and new formulation

- On November 14, 2017, [Noden Pharma announced the FDA approval](#) of [Tektura \(aliskiren\)](#), for the treatment of hypertension in adults and children 6 years of age and older, to lower blood pressure.
 - Previously, Tektura was indicated for the treatment of hypertension in adult patients aged 18 years and older.
 - In addition, Tektura has been approved as a 37.5 mg oral pellet. Previously, it was available as 150 mg and 300 mg tablets.
- According to the American Academy of Pediatrics' [hypertension guidelines](#), the prevalence of clinical hypertension in children and adolescents is ~3.5%.
- The expanded indication for Tektura was approved based on an 8-week efficacy study in 267 pediatric (6 – 17 years of age) hypertensive patients and a 52-week extension study where 208 patients were randomized to Tektura or [enalapril](#).
 - During the initial dose-response phase, Tektura reduced both systolic and diastolic blood pressure in a weight-based dose-dependent manner.
 - At the end of 52 weeks, reductions in blood pressure from baseline were similar in patients receiving Tektura (7.6/3.9 mmHg) and enalapril (7.9/4.9 mmHg).
- Tektura carries a boxed warning for fetal toxicity.
- The recommended dose of Tektura in pediatric patients 6 – 17 years is given orally once daily based on body weight as follows:

| Weight | Recommended dose |
|---------------|--|
| < 20 kg | Tektura is not recommended |
| 20 kg – 50 kg | Starting dose: 75 mg once daily. Maximum dose: 150 mg. |
| > 50 kg | Same as adult dose |

- The recommended adult dose is 150 mg orally once daily. In patients whose blood pressure is not adequately controlled, the daily dose may be increased to 300 mg.
 - Tektura oral pellets may be taken by opening the dispensing capsule, emptying the contents into a spoon and then administering by mouth, follow with milk (dairy or soy-based) or water immediately without chewing or crushing.
 - Consult the drug label for additional administration recommendations for Tektura oral pellets.
- Noden Pharma plans to launch Tektura oral pellets in 2018.