

## Tekturna® (aliskiren) – Expanded indication and new formulation

- On November 14, 2017, Noden Pharma announced the FDA approval of Tekturna (aliskiren), for the treatment of hypertension in adults and children 6 years of age and older, to lower blood pressure.
  - Previously, Tekturna was indicated for the treatment of hypertension in adult patients aged 18 years and older.
  - In addition, Tekturna 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' <u>hypertension guidelines</u>, the prevalence of clinical hypertension in children and adolescents is ~3.5%.
- The expanded indication for Tekturna 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 Tekturna or enalapril.
  - During the initial dose-response phase, Tekturna 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 Tekturna (7.6/3.9 mmHg) and enalapril (7.9/4.9 mmHg).
- Tekturna carries a boxed warning for fetal toxicity.
- The recommended dose of Tekturna in pediatric patients 6 17 years is given orally once daily based on body weight as follows:

Weight	Recommended dose
< 20 kg	Tekturna 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.
- Tekturna 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 Tekturna oral pellets.
- Noden Pharma plans to launch Tekturna oral pellets in 2018.



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