

Prexxartan[®] (valsartan) – New drug approval

- On December 19, 2017, [Medicure announced](#) the FDA approval of [Prexxartan \(valsartan\)](#) oral solution.
- Prexxartan is indicated for the following:
 - Treatment of hypertension (HTN) in adults and children six years and older, to lower blood pressure
 - Treatment of heart failure (HF) (NYHA class II-IV) to reduce the risk of hospitalization for HF in patients who are unable to swallow valsartan tablets
 - To reduce the risk of cardiovascular (CV) death in clinically stable patients with left ventricular failure or left ventricular dysfunction following myocardial infarction (MI) who are unable to swallow valsartan tablets
- Prexxartan is not therapeutically equivalent to the tablet formulation of [Diovan[®] \(valsartan\)](#). A pharmacokinetic study demonstrated that the peak concentration of valsartan with Prexxartan was higher than with Diovan.
- Clinical studies evaluating the antihypertensive effects of valsartan were conducted with a formulation that is not therapeutically equivalent to Prexxartan.
 - Valsartan has demonstrated efficacy in treating adult and pediatric HTN, a reduction in the risk of hospitalization for HF, and a reduction in the risk of CV death in post-MI patients.
- Prexxartan carries a boxed warning for fetal toxicity.
- Prexxartan is contraindicated in patients with known hypersensitivity to any of its components and should not be co-administered with [Tekturna[®] \(aliskiren\)](#) in patients with diabetes.
- Warnings and precautions of Prexxartan include hypotension, impaired renal function, and hyperkalemia.
- The most common adverse reactions with valsartan use for the treatment of HTN were headache, dizziness, fatigue and abdominal pain.
- The most common adverse reactions with valsartan use for the treatment of HF were dizziness, hypotension, diarrhea, arthralgia, back pain, fatigue, and hyperkalemia.
- The most common adverse reactions which caused patients to discontinue valsartan for the treatment of post-MI were hypotension, cough, and increased blood creatinine.
- The recommended doses of Prexxartan are as follows:

| Indication | Starting Dose | Dose Range | Target Maintenance Dose* |
|--------------------------|--|--|--------------------------|
| HTN (adults) | 40 mg or 80 mg twice daily | 40 mg – 160 mg twice daily | -- |
| HTN (ages 6 to 16 years) | 0.65 mg/kg twice daily (up to 40 mg total) | 0.65-1.35 mg/kg twice daily (up to 40 mg - 160 mg total) | -- |
| HF | 40 mg twice daily | 40 mg – 160 mg twice daily | 160 mg twice daily |

| | | | |
|---------|-------------------|-------------------------------|--------------------|
| Post-MI | 20 mg twice daily | 20 mg – 160 mg twice daily | 160 mg twice daily |
|---------|-------------------|-------------------------------|--------------------|

*as tolerated by patient

- Medicare plans to launch Prexxartan during the first half of 2018. Prexxartan will be available as a 4 mg/mL oral solution.



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