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

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

*as tolerated by patient

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