

Biorphen® (phenylephrine) – New drug approval

- On October 22, 2019, [Eton Pharmaceuticals](#) announced the FDA approval of [Biorphen \(phenylephrine\)](#) injection, for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia.
- Biorphen is the first FDA-approved ready-to-use formulation of phenylephrine.
 - Prior to the approval of Biorphen, phenylephrine injection was only approved and available as a highly concentrated formulation that required hospitals to manually dilute the concentrate prior to administration.
- The evidence for the efficacy of Biorphen is derived from studies of phenylephrine hydrochloride in the published literature. The literature support includes 16 studies evaluating the use of intravenous (IV) phenylephrine to treat hypotension during anesthesia.
 - Phenylephrine has been shown to raise systolic and mean blood pressure when administered either as a bolus dose or by continuous infusion following the development of hypotension during anesthesia.
- Warnings and precautions for Biorphen include exacerbation of angina, heart failure, or pulmonary arterial hypertension; peripheral and visceral ischemia; skin and subcutaneous necrosis; bradycardia; renal toxicity; risk of augmented pressor effect in patients with autonomic dysfunction; and pressor effect with concomitant oxytocic drugs.
- The most common adverse reactions with Biorphen use were nausea, vomiting, and headache.
- The recommended initial dose of Biorphen is 40 to 100 mcg administered by IV bolus. Additional boluses may be administered every 1 to 2 minutes as needed; not to exceed a total dosage of 200 mcg. The dosage should be adjusted according to the blood pressure goal.
 - Biorphen must not be diluted before administration as an IV bolus. It is supplied as ready-to-use formulation.
- Eton Pharmaceuticals and their manufacturing partner, Sintetica, plan to launch Biorphen before the end of the year. Biorphen will be available as a 5 mL single-dose ampule for injection.