Giapreza (angiotensin II)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Giapreza
- **Generic name:** Angiotensin II
- **Pharmacological class:** Vasoconstrictor
- **Strength and Formulation:** 2.5mg/mL; per vial; solution for IV infusion after dilution
- **Manufacturer:** La Jolla Pharmaceutical
- **How supplied:** Single-dose vial (1mL, 2mL)—1
- **Legal Classification:** Rx

Indications

- To **increase blood pressure** in septic or other distributive shock

Dosage & Administration

- Give by IV infusion
- **Initially** 20ng/kg/min
- May titrate every 5mins by increments of up to 15ng/kg/min as needed based on BP response; max 80ng/kg/min during first 3hrs of treatment
- **Maintenance dose:** max 40ng/kg/min

Dosage & Administration

- Doses as low as 1.25ng/kg/min may be used
- Once sufficiently improved, down-titrate every 5–15mins by increments of up to 15ng/kg/min based on BP

Considerations for Special Populations

- **Pregnancy:** Insufficient data to determine a drug-associated risk
- **Nursing mothers:** No data available on effects on breastfed child or milk production
- **Pediatric:** Not established
- **Elderly:** No significant difference in safety or efficacy

Warnings/Precautions

- Risk of **thrombosis**
- Use concurrent VTE prophylaxis

Interactions

- Concomitant **ACE inhibitors** may increase response
- Concomitant **ARBs** may decrease response

Adverse Reactions

- Thromboembolic events (eg, DVT)
- Thrombocytopenia
- Tachycardia
- Fungal infection
- Delirium
- Acidosis
- Hyperglycemia
- Peripheral ischemia

Mechanism of Action

- **Angiotensin II** raises blood pressure by vasoconstriction and increased aldosterone release
- Binding to the G-protein-coupled angiotensin II receptor type 1 on vascular cells stimulates Ca^{2+}/calmodulin-dependent phosphorylation of myosin and causes smooth muscle contraction

Clinical Studies

- **ATHOS-3** (Angiotensin II for the Treatment of High-Output Shock) trial was a double-blind study (N=321) of adults with septic or other distributive shock who remained hypotensive despite fluid and vasopressor therapy

Clinical Studies

- Patients were randomized to Giapreza or placebo and were titrated to a target mean arterial pressure (MAP) of ≥75mmHg
- The **primary endpoint** was the percentage of patients who achieved either a MAP ≥75mmHg or ≥10mmHg increase in MAP without an increase in baseline vasopressor therapy at 3 hours

Clinical Studies

- The primary endpoint was achieved in **70%** of patients who received Giapreza vs **23%** of patients who received placebo (treatment effect 47%; *P* <.0001)

Clinical Studies

- The median time to reach target MAP endpoint was **5 minutes** in the Giapreza group
- Effect on MAP was sustained for at least the first 3 hours of treatment

Clinical Studies

- Mortality through Day 28 was **46%** in the Giapreza group vs **54%** in the placebo group (hazard ratio 0.78, 95% CI: 0.57 to 1.07)

- For more clinical data info, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/giapreza/drug/34803/