

Giapreza™ (angiotensin) – New drug approval

- On December 21, 2017, the [FDA announced](#) the approval of [La Jolla Pharmaceutical's Giapreza \(angiotensin\)](#) to increase blood pressure (BP) in adults with septic shock or other distributive shock.
- Distributive shock is the most common type of shock in the inpatient setting, affecting approximately one-third of intensive care unit patients. There are approximately 800,000 distributive shock cases in the U.S. per year. Of these cases, an estimated 90% are septic shock patients. Approximately 300,000 do not achieve adequate BP response with current standard therapy.
 - The inability to achieve or maintain adequate BP results in inadequate blood flow to the body's organs and tissue and is associated with a mortality rate exceeding most acute conditions requiring hospitalization.
- Angiotensin raises BP by vasoconstriction and increased aldosterone release.
- The safety and efficacy of Giapreza was demonstrated in a clinical study of 321 adults with septic or other distributive shock who remained hypotensive despite fluid and vasopressor therapy. Patients were randomized to Giapreza or placebo.
 - The primary endpoint was the percentage of patients who achieved either a mean arterial pressure (MAP) ≥ 75 mmHg or a ≥ 10 mmHg increase in MAP without an increase in baseline vasopressor therapy at 3 hours.
 - The primary endpoint was achieved by 70% of patients treated with Giapreza vs. 23% with placebo ($p < 0.0001$).
- Giapreza carries a warning and precaution for risk of thrombosis.
- The most common adverse reactions ($>10\%$) with Giapreza use were thromboembolic events.
- The recommended starting dose of Giapreza is 20 ng/kg/min via continuous IV infusion. Administration through a central line is recommended.
 - Blood pressure should be monitored and titrated in response to Giapreza.
- La Jolla Pharmaceutical plans to launch Giapreza in March 2018. Giapreza will be available as 2.5 mg/mL and 5 mg/2mL vials.