GIAPREZA™ (angiotensin II) protocol example

THIS EXAMPLE IS PROVIDED FOR INFORMATION ONLY. THIS EXAMPLE SHOULD BE CUSTOMIZED PER INDIVIDUAL INSTITUTION POLICY

Indication:

GIAPREZA is a vasoconstrictor to increase blood pressure in adults with septic or other distributive shock.

Assessment Criteria (please customize and follow your institution criteria)

1. Adult patient (equal or greater than 18 years old) with septic or distributive shock
2. Received adequate volume resuscitation
3. Receiving 1 or more vasopressors and remains hypotensive
4. Venous Thromboembolism (VTE) prophylaxis (pharmacologic preferred, at minimum mechanical)

Administration:

Dosage is Measured in NANOGRAMS (ng) not micrograms (mcg)

- Dilute GIAPREZA in 0.9% sodium chloride prior to use.
- Diluted solution may be stored at room temperature or under refrigeration and should be discarded after 24 hours.
- GIAPREZA must be administered as an intravenous infusion.
- Central venous line administration is recommended*
- The recommended starting dose of GIAPREZA is 20 ng/kg/min via continuous intravenous infusion
    - In the supporting clinical study, the median dose of GIAPREZA was 10 ng/kg/min at 30 minutes[1]

Drug Interactions:

- Angiotensin converting enzyme inhibitors may increase response to GIAPREZA. Angiotensin II receptor blockers may reduce response to GIAPREZA

Titration:

Titrate as frequently as every 5 minutes by increments of up to 15 ng/kg/min as needed.

- During the first 3 hours, the maximum dose should not exceed 80 ng/kg/min.
- Maintenance dose should not exceed 40 ng/kg/min.

Monitoring:

Monitor blood pressure response and titrate GIAPREZA every 5 minutes by increments of up to 15 ng/kg/min, as needed, to achieve or maintain target blood pressure

- Once the underlying shock has sufficiently improved, down-titrate every 5 to 15 minutes by increments of up to 15 ng/kg/min based on blood pressure
- The half-life of IV-administered GIAPREZA is less than 1 minute, which allows for individualized dose adjustment

Adverse Reactions:

The most common adverse reactions reported in greater than 10% in GIAPREZA-treated patients were thromboembolic events. Adverse reactions occurring in ≥4% of patients treated with GIAPREZA and ≥1.5% more often than placebo-treated patients in the ATHOS-3 study were thromboembolic events (including deep vein thrombosis), thrombocytopenia, tachycardia, fungal infection, delirium, acidosis, hyperglycemia, and peripheral ischemia.

*Administration via central line is recommended. If peripheral administration of GIAPREZA is needed, historically, the doses of angiotensin II given via a peripheral line were ≤10 ng/kg/min[2], as a low concentration of 1 mL angiotensin II diluted in 1000 mL normal saline (0.9% sodium chloride [NS]). GIAPREZA should NOT be administered in the same peripheral line as other vasopressors. Blood pressure should be closely monitored.

GIAPREZA™ is marketed by La Jolla Pharmaceutical Company on behalf of La Jolla Pharma LLC, its wholly owned subsidiary.

1.GIAPREZA (angiotensin II) [package insert]. San Diego, CA: La Jolla Pharmaceutical; 2017 2. Data on file

PM-US--0210