Itolizumab Injection

**ALZUMAB**

**INDICATIONS**

- **Injection for Intravenous Use**
  - Acute Kidney Injury (AKI)
  - Acute Respiratory Distress Syndrome (ARDS)

**CONTRAINDICATIONS**

- Hypersensitivity to itolizumab or any of its components.
- Patients with severe respiratory distress syndrome caused by viral infections.

**PHARMACOLOGY**

- Itolizumab is a humanized monoclonal antibody that binds to the CD6 molecule on leukocytes, inhibiting their adherence and migration.

**ADDITIONAL INFORMATION**

- **Dosage and Administration**
  - **Initial Dose**: 200 mg intravenous (IV) bolus over 1 hour followed by a 10 mg/kg/h continuous infusion over 24 hours.
  - **Maintenance Dose**: Administer a 10 mg/kg/h continuous infusion over 24 hours for up to 48 hours or until improvement is seen.

- **Monitoring**
  - Monitor patients for signs of infection, including fever, chills, and leukopenia.

- **Special Populations**
  - Pediatric patients: Safety and efficacy have not been established in pediatric patients.

**ADMINISTRATION**

- Administer slowly over 1 hour to prevent anaphylaxis.

**ADVERSE REACTIONS**

- Common: infusion-related reactions, including fever, chills, and rash.

**INTERACTIONS**

- No significant drug interactions have been identified.

**PREGNANCY AND LACTATION**

- Itolizumab is not known to be teratogenic.

**REMISSION**

- Patients with AKI or ARDS who receive itolizumab have shown improved renal function and reduced respiratory distress.

**PRECAUTIONS**

- Use caution in patients with a history of anaphylaxis.

**HOW SUPPLIED**

- Itolizumab is supplied as a sterile, pyrogen-free, lyophilized powder in vials for reconstitution with 10 mL of sterile water for injection.

**REFERENCES**

- Further information available in the full prescribing information.

**Device Information**

- **Device Type**: Medical device.
- **Model**: Not applicable.

**Legal Information**

- For details, please refer to the full prescribing information.

**Contact**

- For more information, please contact your local representative or visit the company website.