Generic Name:
Immune globulin intravenous, human ? slra 10% liquid
Trade Name:
Asceniv
Company:
Adma Biologics
Notes:

FDA has approved a plasma-derived, polyclonal, intravenous immune globulin (IVIG) for treatment of primary humoral immunodeficiency disease (PIDD or PI) in adults and adolescents aged 12 to 17 years.

Approval was based on a pivotal Phase III clinical study that enrolled 59 patients with PI at nine sites across the United States. Patients received regular infusions of the drug over 1 year. The trial?s primary endpoint evaluated the rate of serious bacterial infections (SBI) in patients treated with the agent. Secondary endpoints included time to first SBI and to first serious infection, days on antibiotics, days off school or work due to infections, all confirmed infections of any kind, and hospitalizations due to infection. No SBIs occurred during the 12-month study period.

The approved labeling will include a boxed warning about potential thrombosis and renal dysfunction or failure. Common adverse events are headache, sinusitis, diarrhea, gastroenteritis viral, nasopharyngitis, upper respiratory tract infection, bronchitis, and nausea.

Medication Monitor Categories:
New Drug Approvals