Dinutuximab

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Brand name: Unituxin® FDA approval: Yes Manufacturer Link

Usage:

Unituxin is supplied in single-use vials of 17.5 mg/5mL. Each vial contains 3.5 mg/mL of dinutuximab, histidine (20mM), polysorbate 20 (0.05%), sodium chloride (150 mM), and water for injection; hydrochloric acid is added to adjust pH to 6.8.

Mechanism:

Neuroblastoma is a rare cancer that forms from immature nerve cells. It usually begins in the adrenal glands but may also develop in the abdomen, chest or in nerve tissue near the spine. Neuroblastoma typically occurs in children younger than five years of age. According to the National Cancer Institute, neuroblastoma occurs in approximately one out of 100,000 children and is slightly more common in boys. There are an estimated 650 new cases of neuroblastoma diagnosed in the United States each year. Patients with high-risk neuroblastoma have a 40 to 50 percent chance of long term survival despite aggressive therapy. Unituxin is an antibody that binds to the surface of neuroblastoma cells. Unituxin is being approved for use as part of a multimodality regimen, including surgery, chemotherapy and radiation therapy for patients who achieved at least a partial response to prior first-line multiagent, multimodality therapy. Three years after treatment assignment, 63 percent of participants receiving the Unituxin combination were alive and free of tumor growth or recurrence, compared to 46 percent of participants treated with RA alone. In an updated analysis of survival, 73 percent of participants who received the Unituxin combination were alive compared with 58 percent of those receiving RA alone.

Side effects:

Common side effects of Unituxin include: severe pain, fever, low platelet counts, infusion reactions, low blood pressure, low levels of salt in the blood (hyponatremia), elevated liver enzymes, anemia, vomiting, diarrhea, low potassium levels in the blood, capillary leak syndrome (which is characterized by a massive leakage of plasma and other blood components from blood vessels into neighboring body cavities and muscles), low numbers of infection-fighting white blood cells (neutropenia and lymphopenia), hives, and low blood calcium levels.