

DINUTUXIMAB (UNITUXIN®)



U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

03/10/2015

The U.S. Food and Drug Administration today approved Unituxin (dinutuximab) as part of first-line therapy for pediatric patients with high-risk neuroblastoma, a type of cancer that most often occurs in young children.

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.

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.