Unituxin® (dinutuximab) – New warnings

- On March 1, 2017 the FDA approved new updates to the *Warnings and Precautions* section of the Unituxin (dinutuximab) drug label.

- Unituxin is indicated, in combination with granulocyte-macrophage colony stimulating factor, interleukin-2 and 13-cis-retinoic acid, for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy.

- The *Warnings and Precautions* subsection, Neurotoxicity, has been updated to include the newly identified risks of prolonged urinary retention, transverse myelitis, and reversible posterior leukoencephalopathy syndrome (RPLS).

    — The adverse reactions of pain, peripheral neuropathy, and neurological disorders of the eye, have also been categorized under the new Neurotoxicity subsection.

- Urinary retention that persists for weeks to months following discontinuation of opioids has occurred in patients treated with Unituxin. Transverse myelitis and RPLS has also occurred in patients treated with Unituxin.

    — Patients should be promptly evaluated if signs or symptoms of transverse myelitis such as weakness, paresthesia, sensory loss, or incontinence occur.
    — Appropriate medical treatment should be instituted in patients that develop signs and symptoms of RPLS during Unituxin therapy.
    — Unituxin should be permanently discontinued in patients who develop transverse myelitis, signs and symptoms of RPLS, or urinary retention that does not resolve upon opioid discontinuation.

- Dosing instructions were revised to include urinary retention, transverse myelitis, and RPLS as adverse reactions requiring permanent discontinuation of Unituxin.

- In support of the new additions to the *Warnings and Precautions* section, the boxed warning was revised to include a subheading for neurotoxicity to encompass other serious neurologic adverse reactions in addition to pain and peripheral neuropathy.

    — Unituxin also carries a boxed warning for serious infusion reactions.

- Similar safety updates were made to the *Adverse Reactions* and *Patient Counseling Information* sections and the Postmarketing Experience subsection of the Unituxin drug label.