Methotrexate (preservative) injection – Label Update

- The FDA approved changes to the Indications and Boxed Warnings sections of Hospira’s methotrexate (preservative) injection label to revise the indication for acute lymphocytic leukemia (ALL) and the boxed warning regarding formulation selection.

- Methotrexate (preservative) injection is now indicated in ALL for use in maintenance therapy in combination with other chemotherapeutic agents.
  
  — Previously, in ALL, methotrexate (preservative) injection was indicated for the prophylaxis of meningeal leukemia and is used in maintenance therapy in combination with other chemotherapeutic agents. Methotrexate (preservative) injection was also indicated in the treatment of meningeal leukemia.
  
  — This revision eliminated references to treatment and prophylaxis of meningeal leukemia.

- Methotrexate (preservative) injection is also approved for the following uses:
  
  — Neoplastic diseases
    - Gestational choriocarcinoma, chorioadenoma destructuens, and hydatidiform mole
    - Breast cancer
    - Epidermoid cancers of the head and neck
    - Mycosis fungoides (cutaneous T cell lymphoma)
    - Lung cancer
    - Lymphomas
    - Osteosarcoma

  — Psoriasis

  — Rheumatoid arthritis including polyarticular-course juvenile rheumatoid arthritis

- The boxed warning for methotrexate injection was revised to clearly communicate that the preserved formulation contains benzyl alcohol and instruct healthcare providers not to use the preserved formulation for intrathecal or high dose therapy.

- Methotrexate is also available generically as a preservative-free injection and tablet.