Videx® and Videx® EC – Updated boxed warning and contraindications

- On January 25, 2018, the FDA approved an update to the *Boxed Warning* and *Contraindications* sections of the Videx (didanosine) and Videx EC (didanosine delayed-release) drug labels regarding the contraindication of didanosine with stavudine.

- Videx and Videx EC are indicated for use in combination with other antiretroviral agents for the treatment of human immunodeficiency virus-1 infection.

- Coadministration of didanosine and stavudine is contraindicated because of the potential for serious and/or life-threatening events notably pancreatitis, lactic acidosis, hepatotoxicity, and peripheral neuropathy.

- Revisions were also made to the *Boxed Warning* and *Warning and Precautions* sections of the Videx and Videx EC drug labels regarding the new contraindication.

    — Previously, the boxed warning stated that the combination of didanosine with stavudine should be used with caution during pregnancy and only recommended if the potential benefits outweighed the potential risks.

- In addition, lipoatrophy was added and fat redistribution was removed from the *Warnings and Precautions* section of the Videx and Videx EC drug labels.

    — Treatment with Videx or Videx EC has been associated with loss of subcutaneous fat, which is most evident in the face, limbs, and buttocks.
    — The incidence and severity of lipoatrophy are related to cumulative exposure, and is often not reversible when Videx or Videx EC treatment is stopped.

- Patients receiving Videx or Videx EC should be frequently examined and questioned for signs of lipoatrophy, and if feasible therapy should be switched to an alternative regimen if there is suspicion of lipoatrophy.