Exondys 51™ (eteplirsen) – New warning

- On February 8, 2018, the FDA approved a *Warning and Precaution* section to the Exondys 51 (eteplirsen) drug label regarding hypersensitivity reactions.

- Exondys 51 is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping.

- Hypersensitivity reactions, including rash and urticaria, pyrexia, flushing, cough, dyspnea, bronchospasm, and hypotension have occurred in patients who were treated with Exondys 51.

    — If a hypersensitivity reaction occurs, institute appropriate medical treatment and consider slowing the infusion or interrupting the Exondys 51 therapy.

- Similar safety information was added to the *Dosage and Administration* section. A *Patient Counseling Information* section was also added to include the safety update.