



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.



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