Attachment

August 7 , 2026

【Therapeutic category】Other agents affecting nervous system and sensory organs

【Non-proprietary name】Viltolarsen

【Safety measure】PRECAUTIONS should be revised.

A revised description is underlined.

Current	Revision
5. PRECAUTIONS CONCERNING INDICATIONS This product should be administered to patients for whom deletion of dystrophin gene treatable by exon 53 skipping (e.g., deletion of exon 43-52, 45-52, 47-52, 48-52, 49-52, 50-52, 52) has been confirmed by genetic testing. In addition, patients enrolled in clinical trials with mutated dystrophin genes should be selected based on a thorough knowledge of the contents of Section “17. CLINICAL STUDIES " and a thorough understanding of the efficacy and safety of this drug. (N/A)	5. PRECAUTIONS CONCERNING INDICATIONS This product should be administered to patients for whom deletion of dystrophin gene treatable by exon 53 skipping (e.g., deletion of exon 43-52, 45-52, 47-52, 48-52, 49-52, 50-52, 52) has been confirmed by genetic testing. In addition, patients enrolled in clinical trials with mutated dystrophin genes should be selected based on a thorough knowledge of the contents of “17. CLINICAL STUDIES" section. Carefully decide whether to start and continue administration after thoroughly understanding the efficacy and safety of this drug and be thoroughly familiar with the contents of “17. CLINICAL STUDIES" section. In addition, the patient's condition should be carefully monitored after administration and the efficacy should be evaluated periodically to determine whether to continue administration. If no effect is observed, administration should be discontinued.

The efficacy and safety of this drug have not been established in patients on long-term mechanical ventilation or in patients with advanced mobility impairment. When administering this drug to these patients, the decision on whether to administer this drug should be made based on consideration of their remaining motor function and other factors. If administration is performed, the patient's condition should be carefully monitored, and the efficacy should be evaluated periodically to determine whether or not to continue administration. If no effect is observed, administration should be discontinued.	The efficacy and safety of this drug have not been established in patients on long-term mechanical ventilation or in patients with advanced mobility impairment. When administering this drug to these patients, the decision on whether to administer this drug should be made based on consideration of their remaining motor function and other factors.

N/A: Not Applicable. No corresponding description is included in the current PRECAUTIONS.