



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of Precautions

Nusinersen sodium

January 10, 2019

Non-proprietary name

Nusinersen sodium

Safety measure

Precautions should be revised in the package insert.

A Clinically Significant Adverse Reactions subsection should be newly added and the following language should be included in the Adverse Reaction section (revised language is underlined):

Hydrocephalus:

Hydrocephalus may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures should be taken.