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

Summary of Investigation Results

Nusinersen sodium

January 10, 2019

Non-proprietary name

Nusinersen sodium

Branded name (Marketing authorization holder)

Spinraza Intrathecal Injection 12 mg (Biogen Japan Ltd)

Indications

Spinal muscular atrophy

Summary of revisions

“Hydrocephalus” should be newly added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of hydrocephalus have been reported in patients treated with nusinersen sodium in Japan and overseas. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

Number of adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years

1 case involving hydrocephalus has been reported to date (a causal relationship with the product could not be ruled out in this case.)

No patient mortalities have been reported to date.

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