PRODUCT FACT SHEET

SPINRAZA™ (nusinersen) injection 5mL
12mg • 28mg • 50mg

COMPANY: Biogen®

PRODUCT TRADE NAME: SPINRAZA®

GENERIC NAME: Nusinersen

INDICATION: SPINRAZA is a survival motor neuron-2 (*SMN2*)-directed antisense oligonucleotide indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.[1]

STORAGE REQUIREMENTS: Store in a refrigerator between 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze.[1] See product packaging and Prescribing Information for complete list of instructions.

RECOMMENDED DOSAGE:
SPINRAZA is administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures.[1]

The 2 dosing regimen options for SPINRAZA consist of loading followed by maintenance dosages.[1]

For patients new to SPINRAZA Low Dose Regimen: Administer a total of 4 loading doses as follows: One 12 mg dose every 14 days for 3 doses, then a fourth 12 mg dose 30 days after the third dose. Administer 12 mg once every 4 months starting 4 months after the last loading dose.[1]

For patients new to SPINRAZA High Dose Regimen: Administer a total of 2 loading doses as follows: One 50 mg dose followed by a second 50 mg dose 14 days later. Administer 28 mg once every 4 months starting 4 months after the last loading dose.[1]

If transitioning from Low Dose SPINRAZA to High Dose SPINRAZA: Administer a single 50 mg bolus dose at least 4 months (+/-14 days) after the last 12 mg maintenance dose, followed by a 28 mg maintenance dose once every 4 months thereafter.[1]

Additional clinical benefit in patients who transition from Low Dose SPINRAZA to High Dose SPINRAZA has not been established in a controlled study.[1]

Not shown actual size.

SPINRAZA 12 mg/5 mL vial

SPINRAZA 28 mg/5 mL vial

SPINRAZA 50 mg/5 mL vial

How supplied[1]	12 mg/5 mL vial	28 mg/5 mL vial	50 mg/5 mL vial
Packaging[1]	Single-dose glass vial, one vial per carton	Single-dose glass vial, one vial per carton	Single-dose glass vial, one vial per carton
Carton dimensions	2.28" × 2.05" × 3.15"	2.28" × 2.05" × 3.15"	2.28" × 2.05" × 3.15"
National Drug Code (NDC) number[1]	**64406-058-01**	**64406-036-01**	**64406-037-01**
WAC	[$152,000]	[$152,000]	[$271,000]
HCPCS code/J-code[2]	[Hospital outpatient/office: J2326, Injection, nusinersen, 0.1 mg]		
Example International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes[3]	**G12.0** - Infantile spinal muscular atrophy, type I [Werdnig-Hoffmann] **G12.1** - Other inherited spinal muscular atrophy Adult form spinal muscular atrophy Childhood form, type II spinal muscular atrophy Distal spinal muscular atrophy Juvenile form, type III spinal muscular atrophy [Kugelberg-Welander] **Note:** Be sure to use the appropriate code for SMA diagnosis so it will be accepted on the claim form by the health plan. Using codes G12.8 (other SMAs and related syndromes) or G12.9 (SMA, unspecified) may result in a claim denial because SMA type is not specified.		

INDICATION

SPINRAZA® (nusinersen) is indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

IMPORTANT SAFETY INFORMATION

Coagulation abnormalities and thrombocytopenia, including acute severe thrombocytopenia, have been observed after administration of some antisense oligonucleotides. Patients may be at increased risk of bleeding complications.

In the sham-controlled studies for patients with infantile-onset (Study 1) and later-onset (Study 2) SMA who received Low Dose Regimen (12 mg loading doses/12 mg maintenance doses), 24 of 146 SPINRAZA-treated patients (16%) with high, normal, or unknown platelet count at baseline developed a platelet level below the lower limit of normal, compared to 10 of 72 sham-controlled patients (14%). Two SPINRAZA-treated patients developed platelet counts <50,000 cells per microliter, with the lowest level of 10,000 cells per microliter recorded on study day 28. In patients who received High Dose Regimen (50 mg loading doses/28 mg maintenance doses), decreases in platelet counts were also observed.

Please see additional Important Safety Information on next page and full Prescribing Information.

IMPORTANT SAFETY INFORMATION (cont'd)

Renal toxicity, including potentially fatal glomerulonephritis, has been observed after administration of some antisense oligonucleotides. SPINRAZA is present in and excreted by the kidney. In Study 1 and Study 2, 71 of 123 SPINRAZA-treated patients (58%) had elevated urine protein, compared to 22 of 65 sham-controlled patients (34%).

Laboratory testing and monitoring to assess safety should be conducted. Perform a platelet count, coagulation laboratory testing, and quantitative spot urine protein testing at baseline and prior to each dose of SPINRAZA and as clinically needed.

Severe hyponatremia was reported in an infant treated with SPINRAZA requiring salt supplementation for 14 months.

Cases of rash were reported in patients treated with SPINRAZA.

SPINRAZA may cause a reduction in growth as measured by height when administered to infants, as suggested by observations from the controlled study. It is unknown whether any effect of SPINRAZA on growth would be reversible with cessation of treatment.

The most common adverse reactions in the Low Dose Regimen (≥20% of SPINRAZA-treated patients and ≥5% more frequently than in control patients) that occurred in the infantile-onset controlled study were lower respiratory infection and constipation. Serious adverse reactions of atelectasis were more frequent in SPINRAZA-treated patients (18%) than in control patients (10%). Because patients in this controlled study were infants, adverse reactions that are verbally reported could not be assessed. The most common adverse reactions that occurred in the later-onset controlled study were pyrexia, headache, vomiting, and back pain. Post-lumbar puncture syndrome has also been observed after the administration of SPINRAZA.

The most common adverse reactions in the High Dose Regimen (≥10% of SPINRAZA-treated patients and ≥5% more frequently than control patients from Study 1) that occurred in patients with infantile-onset SMA were pneumonia, COVID-19, pneumonia aspiration, and malnutrition. COVID-19 was not discovered at the time of Study 1.

Please see additional Important Safety Information on previous page and full Prescribing Information.

References: 1. SPINRAZA. Prescribing Information. Biogen; 2026. **2.** HCPCS Code J2326. https://hcpcs.codes/j-codes/J2326/. Accessed March 24, 2026. **3.** National Center for Health Statistics – ICD-10-CM. https://icd10cmtool.cdc.gov/. Accessed March 24, 2026.

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