

For the more than **4600 adults** who have been treated with SPINRAZA worldwide, victories are personal.\*

\*Based on commercial patients, early access patients, and clinical trial participants through May 2022.

### **INDICATION**

SPINRAZA® (nusinersen) is a prescription medicine used to treat spinal muscular atrophy (SMA) in pediatric and adult patients.

### **SELECTED IMPORTANT SAFETY INFORMATION**

**Increased risk of bleeding complications** has been observed after administration of similar medicines. Your healthcare provider should perform blood tests before you start treatment with SPINRAZA and before each dose to monitor for signs of these risks. Seek medical attention if unexpected bleeding occurs.

# People living with SMA will experience motor function loss throughout their lives.

Spinal muscular atrophy (SMA) is a genetic disorder caused by a lack of survival motor neuron (SMN) protein, a protein that's key for muscle development and movement. Without this protein, motor neurons cannot send signals to muscles from the central nervous system (CNS), and muscles get weaker and weaker.

Natural history shows that all people living with SMA will experience motor function loss throughout their lives. For people living with later-onset SMA, these losses may become more noticeable with age.

## Genetic testing can confirm an SMA diagnosis.



Genetic testing is often required to start treatment. Ask your healthcare provider (HCP) for more information about genetic testing.

# It's impossible to know when you will experience motor function loss.

The rate of motor function loss varies from person to person, and there is no sure way to tell when someone living with SMA will experience muscle function loss. Although some people may experience periods where motor function appears stable, people living with later-onset SMA will experience motor function loss over time. Below are some key facts about SMA disease progression.



### Motor function loss can become more obvious over time.

It can be hard to notice motor function loss with annual checkups because it may be happening slowly. But that doesn't mean it isn't happening. Such loss becomes more obvious as it continues over time.



### Type and age aren't true predictors of motor function loss.

Because everyone experiences SMA differently, there is no way to predict when motor function loss will happen or even who will experience it.

Talk to your doctor about changes in your motor function.

These are moments and stories. These are personal victories. This is SPINRAZA.



### 13,000+

have been treated with SPINRAZA worldwide\*

\*Based on commercial patients, early access patients, and clinical trial participants through May 2022.



## From 3 days<sup>†</sup> to 80 years old,<sup>‡§</sup>

there's someone from almost every age group who has taken SPINRAZA

†Includes clinical trial patients.

<sup>‡</sup>Clinical studies of SPINRAZA did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger patients. Clinical studies included patients from 3 days to 16 years of age at first dose.

§Based on commercial patients in the US (including Puerto Rico) through May 2022.



### 4600+ adults

have been treated with SPINRAZA worldwide\*

\*Based on commercial patients, early access patients, and clinical trial participants through May 2022.

### **SELECTED IMPORTANT SAFETY INFORMATION**

**Increased risk of kidney damage, including potentially fatal acute inflammation of the kidney**, has been observed after administration of similar medicines. Your healthcare provider should perform urine testing before you start treatment with SPINRAZA and before each dose to monitor for signs of this risk.



# SMA is a disease of the CNS. SPINRAZA is delivered directly into the CNS.

People with SMA can't generate enough SMN protein, the protein their motor neurons need to function. That's where SPINRAZA can help.

- // Gets to the source of motor neuron loss
- // While you continue on treatment, SPINRAZA helps your body's SMN protein production

## SPINRAZA specifically targets an underlying cause of muscle weakness.

People with SMA can't make enough SMN protein because they have a mutated or missing survival motor neuron 1 (SMN1) gene. The gene they do have, SMN2, does not produce enough SMN protein that is needed for motor neurons to survive.







7-year old Emma explains how SPINRAZA works. Watch at SPINRAZA.com/HowSPINRAZAWorks



# The effect of SPINRAZA has been studied in the longest clinical trial program in SMA to date.

### **CHERISH** pivotal study

Studied changes in motor function in 126 nonambulatory individuals with later-onset SMA

## CS2/CS12 supportive study

Studied overall safety and changes in motor function in 28 ambulatory and nonambulatory individuals with later-onset SMA

This list does not include all SPINRAZA clinical trials.

### **SELECTED IMPORTANT SAFETY INFORMATION**

**The most common side effects of SPINRAZA include** lower respiratory infection, fever, constipation, headache, vomiting, back pain, and post-lumbar puncture syndrome.

These are not all of the possible side effects of SPINRAZA. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**Before taking SPINRAZA**, tell your healthcare provider if you are pregnant or plan to become pregnant.

This information is not intended to replace discussions with your healthcare provider.

## Study information

Studies use scales to track improvements, but these scales can often be complex or unfamiliar. Definitions for all the scales in this brochure are listed for you below.

### Motor function scales

### // HFMSE

The Hammersmith Functional Motor Scale—Expanded is an SMA-specific scale used to measure how well someone can do daily tasks like lifting their head, sitting, and stair-climbing. Each item is scored from 0 to 2, with a maximum score of 66.

### // RULM

The Revised Upper Limb Module is a scale used to measure upper limb strength and function. It measures how well someone can do daily tasks like pushing buttons and opening containers. Each item is scored from 0 to 2, with a maximum score of 37.

### // ULM

The Upper Limb Module is just a slightly older version of the RULM. See definition above. It is scored from 0 to 18 points, with higher scores indicating better function.

### // 6MWT

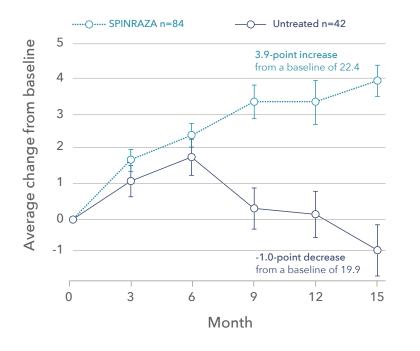
The 6-Minute Walk Test is used to measure how far a person can walk in 6 minutes.



# Individuals treated with SPINRAZA, with later-onset SMA experienced improvements in overall motor function.

- // Who: 126 children ages 2-9 years with later-onset SMA
- **// Study time:** 15 months
- // Primary outcome: Changes in motor function, measured with HFMSE
- // Secondary outcomes: Changes in upper limb function, measured with RULM and percentage of individuals who had a clinically meaningful (3 or more points) improvement from baseline in HFMSE score
- // Limitation: The dosing schedule was different from the approved SPINRAZA dosing schedule
- // Safety: The most common side effects were fever (43%), headache (29%), vomiting (29%), and back pain (25%)

# Primary outcome: Average change from baseline in HFMSE total score at 15 months



Those treated with SPINRAZA significantly improved their motor function

Motor function began to steadily improve in just 6 months compared to the untreated group

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SPINRAZA® (nusinersen) injection 12 mg/5 mL

A 1- or 2-point improvement in HFMSE is considered a positive change, and 3 or more point improvement a clinically meaningful change.

Secondary outcome: Percentage of individuals with a 3 or more point increase from baseline in HFMSE score

Treated with SPINRAZA

56.8%

Untreated

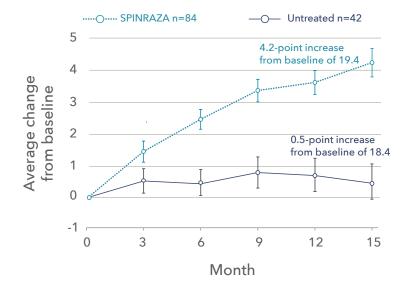
**26.3**%



### **SELECTED IMPORTANT SAFETY INFORMATION**

**Increased risk of kidney damage, including potentially fatal acute inflammation of the kidney**, has been observed after administration of similar medicines. Your healthcare provider should perform urine testing before you start treatment with SPINRAZA and before each dose to monitor for signs of this risk.

# Secondary outcome: Average change from baseline in upper limb function score at 15 months



Those treated with SPINRAZA on average significantly increased their upper limb function

# Individuals within this study, on average, showed improvements in overall motor function and walking ability.

- // Who: 28 individuals ages 2 to 16 years old with later-onset SMA treated with SPINRAZA
- // Study time: approximately 3 years
- // Primary outcome: Safety of SPINRAZA
- // Other outcomes: The safety and longer-term effects of SPINRAZA on overall motor function, upper limb function, and walking ability were also studied
- // Limitations: The dosing was different than the approved SPINRAZA schedule and these studies had no controls and small number of participants
- // Safety: Side effects were similar to those reported in the pivotal trials

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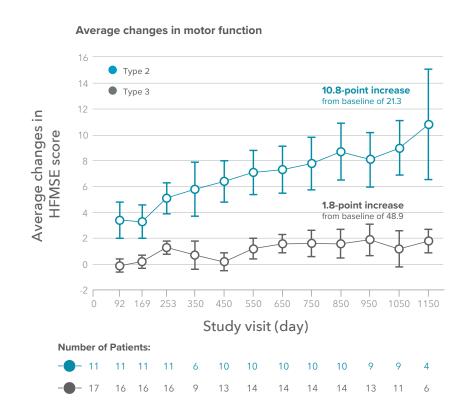
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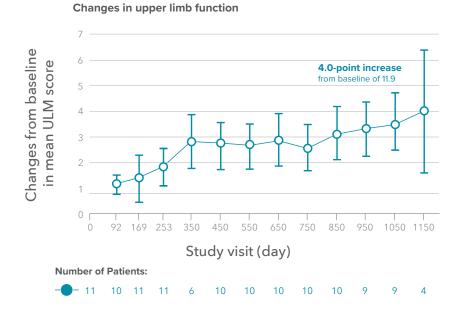


Individuals treated with SPINRAZA, on average, saw increases in motor function over 3 years.



CS2/CS12 SUPPORTIVE STUDY

Non-ambulatory individuals treated with SPINRAZA saw improvement from baseline in their upper limb function.



56% (5/9) individuals saw clinically meaningful improvements in ULM by approximately year 3 (defined as ≥2-point increase from baseline)\*

\*Due to a gap between study visits, some data points do not contain results for all children.

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100% (8/8) of who had the ability to walk achieved improvements in their walking distance by approximately year 3 (improvements defined as ≥ 30 meters from baseline)\*

 $^{\star}$ Due to a gap between study visits, some data points do not contain results for all children.

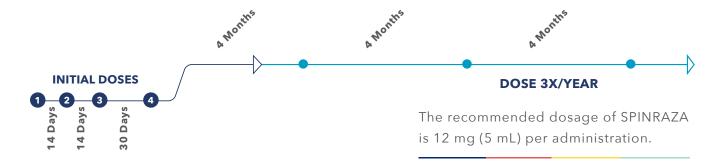
# AVERAGE WALKING DISTANCE INCREASED

301 feet (92 m)

1 of the 11 with Type 2 SMA gained the ability to walk. 2 of the 4 with Type 3 SMA regained the ability to walk.

## SPINRAZA° (nusinersen) injection 12 mg/5 mL

# Dosing designed to get your body the medicine it needs, when it needs it.



SPINRAZA is an intrathecal injection, or an injection into the fluid in the spine, by a healthcare provider (HCP) experienced in performing lumbar punctures.

The dosing schedule begins with 4 initial loading doses; the first 3 occur in 14-day intervals and the fourth dose 30 days after the third dose. After these initial doses, SPINRAZA is administered in maintenance doses 3 times a year. Ask your HCP for additional information about the dosing schedule and treatment procedure.



### **Blood and urine testing**

Because an increased risk of bleeding and kidney damage has been seen with similar medications, individuals taking SPINRAZA may be at similar risk. It is recommended your HCP perform blood and urine testing once before starting treatment and again before each dose to monitor for signs of these risks.

### **SELECTED IMPORTANT SAFETY INFORMATION**

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# There are SPINRAZA treatment centers all across the US.

Find one at <a href="mailto:SPINRAZA.com/locator">SPINRAZA.com/locator</a>



"With SPINRAZA, my journey continues to unfold."

–Lauren

## SMA360° Your SPINRAZA circle of support

Biogen's SMA360° support program provides certain services that address nonmedical barriers to access.\*



Treatment coordination



SPINRAZA education



Insurance benefits investigation



Financial assistance for eligible individuals

\*SMA360° services from Biogen are available only to those who have been prescribed SPINRAZA. SMA360° is intended for US residents only.

See all of the SMA360° support services at <u>SPINRAZA.com/support</u>



Join our community.



Speak with a Lead Case Manager 1-844-477-4672 Monday through Friday from 8:30 am to 8:00 pm ET



With SMA360°, you get a full circle of support

Use your phone's camera to scan this code to learn more

"My SMA360 team has been phenomenal. They've been warm, caring, and also very knowledgeable."

–lan

#### INDICATION AND IMPORTANT SAFETY INFORMATION



### **INDICATION**

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Please click for full **Prescribing Information**.

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Individual results may vary based on several factors, including severity of disease, initiation of treatment, and duration of therapy.



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