



ISEMBYLD™
(apitegromab-mstn) injection
150mg/3mL

IT'S TIME TO DIRECTLY TARGET MUSCLE IN SMA

Mindy

Treated with ISEMBYLD
Paid spokesperson

ISEMBYLD is a prescription medicine used to treat **spinal muscular atrophy (SMA)** in adults and children 2 years of age and older who are currently receiving a survival motor neuron 2 (SMN2)-targeted treatment.

IMPORTANT SAFETY INFORMATION

Before taking ISEMBYLD, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of low bone density or bone fractures
- are pregnant or plan to become pregnant. If you are pregnant or are planning to become pregnant, ask your healthcare provider for advice before taking this medicine. It is not known if ISEMBYLD will harm your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with ISEMBYLD
- are breastfeeding or plan to breastfeed. It is not known if ISEMBYLD passes into breast milk. Talk to your healthcare provider about the best way to feed your baby while on treatment with ISEMBYLD

Please see additional Important Safety Information throughout and full Prescribing Information and Patient Information.

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IMPORTANT SAFETY INFORMATION

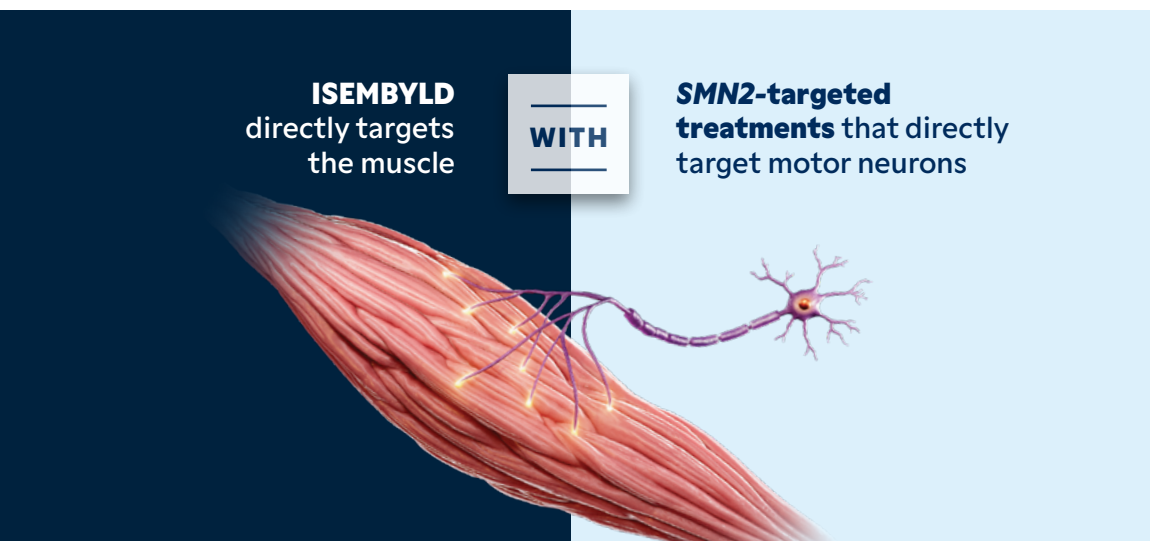
Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Keep a list of them to show your healthcare provider, including your pharmacist, when you get a new medicine.

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ISEMBYLD is the first and only FDA-approved treatment for SMA to directly target the muscle

ISEMBYLD is used to treat SMA in adults and children 2 years of age and older who are currently receiving an *SMN2*-targeted treatment.

**Explore a muscle-targeted treatment
approach to your neuromuscular condition.**



Taken with *SMN2*-targeted treatments like Spinraza[®] (nusinersen) and Evrysdi[®] (risdiplam), ISEMBYLD is designed to improve motor function beyond *SMN2*-targeted treatment alone.*

*Spinraza is a registered trademark of Biogen MA Inc. Evrysdi is a registered trademark of Genentech, Inc.

IMPORTANT SAFETY INFORMATION

What are the possible side effects of ISEMBYLD?

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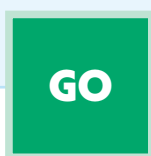
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ISEMBYLD works by blocking myostatin, a protein that limits muscle growth

Myostatin is part of a natural system in the body for regulating muscle size. But for people living with SMA, blocking myostatin may represent an opportunity.



Myostatin acts as a natural stop sign by sending a signal to the muscle to stop growing



ISEMBYLD blocks myostatin, allowing the muscle to receive the signal to grow

Ask your doctor about ISEMBYLD.

[Download the Doctor Discussion Guide](#)

IMPORTANT SAFETY INFORMATION

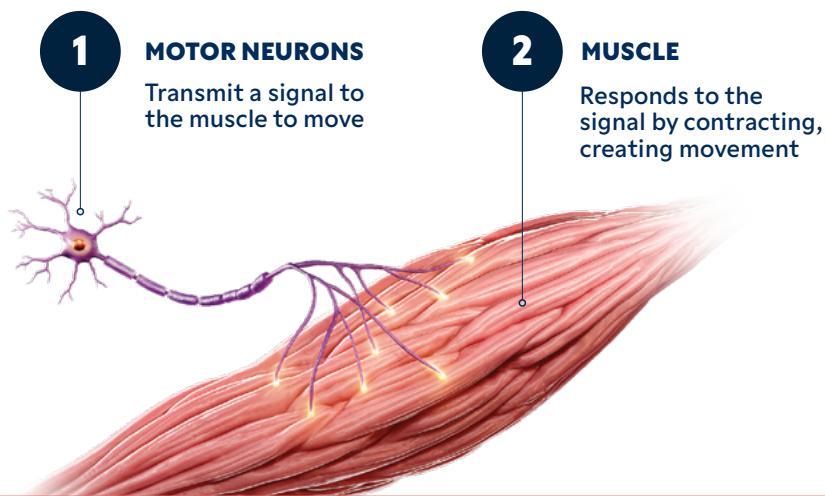
The most common side effects of ISEMBYLD include:

- upper respiratory tract infections
- headache
- vomiting
- stomach flu (gastroenteritis)
- cough
- sore throat (pharyngitis)
- viral infections
- hypersensitivity

These are not all of the possible side effects of ISEMBYLD. Call your healthcare provider for medical advice about side effects.

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SMA affects both motor neurons and the muscle



SMN2-targeted treatments have advanced SMA care by directly targeting motor neurons

These treatments are effective at supporting improvements in motor function. But direct targeting of another key component of the motor unit, **the muscle**, provides further opportunity.

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Even with **SMN2**-targeted treatments, the progressive nature of SMA can lead to ongoing motor function decline



Clinical studies of patients on **SMN2**-targeted treatments (nusinersen or risdiplam) have demonstrated that these treatments help to improve motor function. Motor function was measured by the Hammersmith Functional Motor Scale—Expanded (HFMSE), one of several tests that assesses motor function in daily life.

However, long-term studies of **SMN2**-targeted treatment have shown that scores on the HFMSE trend downward as time goes on.^{a,b}

These long-term data are from studies that do not include a comparison with an untreated placebo control group.^c Though these studies are useful, the findings are not as definitive as studies that include a control group.

Motor neurons and muscle work together to power motor function, but decline can continue despite **SMN2-targeted treatment. That's why it's important to directly target both the motor neuron and the muscle.**

^aData on nusinersen are based on 2 studies: CHERISH, a phase 3, randomized, double-blind, sham-controlled study to evaluate the efficacy and safety of nusinersen (low-dose regimen, 12 mg) in children with later-onset SMA; and SHINE, an open-label extension study for patients with SMA who previously participated in investigational studies of nusinersen, such as CHERISH.

^bData on risdiplam are based on a study called SUNFISH, a 2-part clinical trial of risdiplam in a broad and heterogeneous patient population with types 2 and 3 SMA (aged 2-25 years).

^cPlacebo is a substance that has no therapeutic effect.

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SAPPHIRE: a closer look at the study behind ISEMBYLD FDA approval

PURPOSE: Assess safety and determine whether ISEMBYLD improved motor function in adults and children who were on an *SMN2*-targeted treatment.

188
people
participated

Age range and gender

- Primary Study Group:
2-12 years old (average age 8)
- Additional Study Group:
13-21 years old (average age 16)
- 50% male, 50% female

Over the 52 weeks of the study

- Participants were treated every 4 weeks
- Motor function was assessed approximately every 8 weeks

What treatments were the participants receiving, and for how long?

# OF PEOPLE	TREATMENT	DURATION
139 of 188 people	Spinraza® (nusinersen)	5-6 years average
49 of 188 people	Evrysdi® (risdiplam)	3 years average

IMPORTANT SAFETY INFORMATION

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- **Fractures.** Treatment with ISEMBYLD may increase the risk of bone fractures, including serious fractures. Bone fractures may happen with or without a fall or other injury. Your healthcare provider may consider stopping treatment with ISEMBYLD if you experience a bone fracture during treatment

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What was their level of mobility?

100% of participants were non-ambulatory (unable to walk independently without aids or orthotics over 10 steps).

How was the study set up?

Participants continued on their SMN2-targeted treatment while they were treated with ISEMBYLD or a placebo (ie, a substance with no therapeutic effect) every 4 weeks over the course of a year. Motor function was assessed approximately every 8 weeks. At the end of the study, motor function changes were compared between the group receiving ISEMBYLD with their SMN2-targeted treatment and the group receiving SMN2-targeted treatment alone.



Christopher

Treated with ISEMBYLD.
Paid spokesperson.

IMPORTANT SAFETY INFORMATION

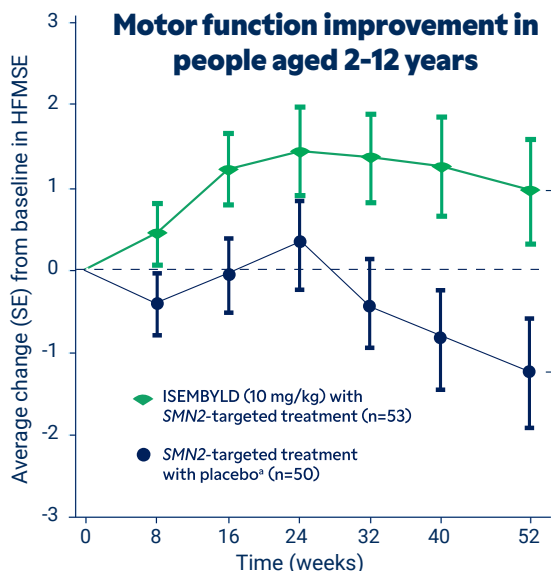
The most common side effects of ISEMBYLD include:

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- headache
- vomiting
- stomach flu (gastroenteritis)
- cough
- sore throat (pharyngitis)
- viral infections
- hypersensitivity

These are not all of the possible side effects of ISEMBYLD. Call your healthcare provider for medical advice about side effects.

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ISEMBYLD is proven to improve motor function in SMA



**2.2
points**

That is a meaningful improvement in HFMSE score after 1 year when people taking ISEMBYLD with an SMN2-targeted treatment (Spinraza® [nusinersen] or Evrysdi® [risdiplam]) were compared with people taking an SMN2-targeted treatment alone.

Standard error (SE) bars are used to show the precision of the average result observed in each study group. Smaller error bars indicate more consistent results across people in the study and greater confidence that the average is a reliable estimate, whereas larger error bars indicate greater variation and less certainty.

^aPlacebo is a substance that has no therapeutic effect.

HFMSE=Hammersmith Functional Motor Scale-Expanded.

Motor function improvement was similar between the child study group and the adolescent and adult study group.^b



^bMotor function improvements were consistent among children (aged 2-12 years) and adolescents and adults (aged 13-21 years) in the study.

IMPORTANT SAFETY INFORMATION

Before taking ISEMBYLD, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of low bone density or bone fractures
- are pregnant or plan to become pregnant. If you are pregnant or are planning to become pregnant, ask your healthcare provider for advice before taking this medicine. It is not known if ISEMBYLD will harm your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with ISEMBYLD
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Ongoing ISEMBYLD treatment matters

In the SAPPHIRE study, clinically meaningful improvements in motor function for people taking ISEMBYLD with an SMN2-targeted treatment compared to people taking an SMN2-targeted treatment alone were seen at 52 weeks (the last measured timepoint in the study). **That is why it's important to continue treatment with ISEMBYLD and discuss your progress with your doctor.**

How was motor function measured in the study?

HFMSE was the primary scale used to measure whether ISEMBYLD improved motor function after 52 weeks of treatment. Functional activities tested include lying down, head lifting, rolling, sitting up, and standing.



98%

of people in the study chose to stay on ISEMBYLD and entered a long-term observational study

The time is now. Talk to your doctor to see whether ISEMBYLD is right for you.

[Download the Doctor Discussion Guide](#)

IMPORTANT SAFETY INFORMATION

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ISEMBYLD has a well-established safety profile

The most common side effects reported with ISEMBYLD were:

- Upper respiratory tract infections
- Vomiting
- Cough
- Viral infections
- Headache
- Stomach flu (gastroenteritis)
- Sore throat (pharyngitis)
- Hypersensitivity

These are not all of the possible side effects of ISEMBYLD. Call your doctor for medical advice about side effects.

Treatment with ISEMBYLD may increase the risk of bone fractures, including serious fractures. Bone fractures may happen with or without a fall or other injury. Your healthcare provider may consider stopping treatment with ISEMBYLD if you experience a bone fracture during treatment.

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DISCONTINUATIONS
due to adverse events during the study

IMPORTANT SAFETY INFORMATION

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How ISEMBYLD is administered



ISEMBYLD is given as an intravenous (IV) infusion every **4 weeks** while on treatment, meaning that it is infused into a vein in the hand or arm.



Based on eligibility, the infusion can be **administered by a healthcare professional** with the flexibility of choosing between 3 locations.



Do not stop treatment with ISEMBYLD unless your healthcare provider tells you to.

Your healthcare provider will determine the amount of ISEMBYLD needed based on your current weight.

If you miss a dose of ISEMBYLD:

- ISEMBYLD should be given (administered) as soon as possible and then restart the dosing schedule 4 weeks after the missed dose is given, or
- the dose can be skipped and the next dose can be given as originally scheduled.

What could ISEMBYLD mean for you?

Talk to your doctor today.

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If you and your doctor decide ISEMBYLD™ (apitegromab-mstn) is right for you...

You can enroll in Scholar Rock Supports, a patient support program designed to meet you where you are.

Scholar Rock Supports is built around the idea that no one should have to navigate treatment alone. Once enrolled, you'll be supported by an experienced and dedicated team that helps guide your experience and coordinates the right resources based on your individual needs.

Here's how to enroll:

1



Complete the Scholar Rock Supports enrollment form with your doctor by visiting ScholarRockSupports.com

2



You or your legal representative and your prescribing doctor must **sign the form**—you can sign it digitally with the eConsent option

3



Your doctor's office will **fax the completed form** to Scholar Rock Supports



We're your ROCC

After your enrollment form is completed, your **ROCC (Rx Onboarding and Care Coordinator)** will reach out and support you as you prepare for treatment and throughout your treatment journey with things like:

- ✓ Navigating insurance
- ✓ Understanding costs and copays
- ✓ Discussing treatment expectations
- ✓ Caregiver resources and guidance
- ✓ Infusion day planning and support



Real Scholar Rock
Supports dedicated
team members.



For more information:

Call Scholar Rock Supports at [1-833-777-5444](tel:1-833-777-5444)

Monday–Friday, 8AM–8PM ET

Visit [ScholarRockSupports.com](https://www.ScholarRockSupports.com)



“I remind myself that everyone’s journey is different. Focusing on today and giving treatment the time it needs helps me stay grounded and hopeful.”

- Ryan

Treated with ISEMBYLD. Paid spokesperson.
Individual patient experience. Results may vary.

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INDICATION & IMPORTANT SAFETY INFORMATION

What is ISEMBYLD (apitegromab-mstn)?

ISEMBYLD is a prescription medicine used to treat spinal muscular atrophy (SMA) in adults and children 2 years of age and older who are currently receiving a survival motor neuron 2 (SMN2)-targeted treatment.

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- | | |
|--------------------------------------|---------------------------------|
| • upper respiratory tract infections | • headache |
| • vomiting | • stomach flu (gastroenteritis) |
| • cough | • sore throat (pharyngitis) |
| • viral infections | • hypersensitivity |

These are not all of the possible side effects of ISEMBYLD. Call your healthcare provider for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <http://www.fda.gov/medwatch> or call 1-800-FDA-1088. Please see full [Prescribing Information](#) and [Patient Information](#).

ISEMBYLD™

(apitegromab-mstn) injection
150mg/3mL



WHAT IT DOES

It blocks a process that limits muscle growth, enabling your muscles to receive the message to grow.



WHO IT'S FOR

It's for adults and children aged 2 years and older who are on SMN2-targeted treatments (Spinraza® [nusinersen] or Evrysdi® [risdiplam]).



HOW IT HELPS

It's designed to improve motor function beyond SMN2-targeted treatment alone.



Ava

Treated with ISEMBYLD.
Paid spokesperson.

ISEMBYLD is a prescription medicine used to treat spinal muscular atrophy (SMA) in adults and children 2 years of age and older who are currently receiving a survival motor neuron 2 (SMN2)-targeted treatment.

The most common side effects reported with ISEMBYLD were upper respiratory tract infections, vomiting, cough, viral infections, headache, stomach flu (gastroenteritis), sore throat (pharyngitis), and hypersensitivity.

Talk to your doctor about ISEMBYLD

For more information, visit [ISEMBYLD.com](https://www.isebyld.com).

Follow us @ISEMBYLD



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