

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

Infusion Guide

ISEMBYLD is the first and only FDA-approved muscle-targeted treatment for SMA¹

FOR US HEALTHCARE PROFESSIONALS

FDA=US Food and Drug Administration; SMA=spinal muscular atrophy.

INDICATION

ISEMBYLD is indicated for the treatment of spinal muscular atrophy (SMA) in adults and pediatric patients 2 years of age and older who are currently receiving a survival motor neuron 2 (SMN2)-targeted treatment.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Fractures

ISEMBYLD may increase the risk of fractures, including serious fractures. Use with caution in patients with a history of low bone density or multiple fractures. In patients who experience fractures, weigh the risks and benefits of continuing ISEMBYLD.

Please see additional Important Safety Information throughout and full [Prescribing Information](#).

THIS INFUSION GUIDE WILL HELP PROVIDE GUIDANCE FOR PREPARATION AND ADMINISTRATION.

Your Road Map for Infusing ISEMBYLD

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IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥20% of patients treated with ISEMBYLD and more frequent than placebo) were upper respiratory tract infections, vomiting, cough, other viral infections, headache, gastroenteritis, pharyngitis, and hypersensitivity.

Please see additional Important Safety Information throughout and full [Prescribing Information](#).

Introduction to ISEMBYLD: The First Muscle-Targeted Treatment for SMA¹

The recommended dose of ISEMBYLD is 10 mg/kg administered once every 4 weeks as an intravenous (IV) infusion over approximately 1 to 2 hours at an infusion rate no greater than 150 mL/hour.¹

If a dose of ISEMBYLD is missed, follow guidelines on [page 7](#).

ISEMBYLD injection is a sterile, preservative-free, clear to moderately opalescent, colorless to slightly yellow solution supplied in a single-dose glass vial for intravenous use.

Each 3 mL single-dose vial contains 150 mg ISEMBYLD and histidine (4.44 mg), L-histidine hydrochloride monohydrate (6.57 mg), sodium chloride (22.80 mg), polysorbate 80 (0.6 mg), and Water for Injection, USP. Hydrochloric acid was added to adjust the pH. The pH is approximately 6.0.¹

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IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS

Pregnancy and Lactation

Based on animal data, ISEMBYLD may cause fetal harm. There are no adequate data on the developmental risk associated with the use of ISEMBYLD in pregnant women.

There are no data on the presence of ISEMBYLD in human milk, the effects on the breastfed infant, or the effects of the drug on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ISEMBYLD, and any potential adverse effects on the breastfed infant.

Females and Males of Reproductive Potential

Based on animal data, ISEMBYLD may affect male and/or female reproductive function.

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

Proper Storage and Handling¹

Once you receive ISEMBYLD, be sure to store it according to proper procedures:

- Store ISEMBYLD vials 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
- Do not shake
- Discard unused portion
- The diluted solution should be administered immediately after preparation. If not used immediately, store the infusion bag, protected from light, either at room temperature (20°C to 25°C [68°F to 77°F]) or in a refrigerator at 2°C to 8°C (36°F to 46°F) for up to 4 hours (including preparation and infusion time). Do not freeze

Essential Supplies to Infuse ISEMBYLD¹

- ISEMBYLD single-dose vials
- Sterile syringe
- Infusion set containing 0.2 or 0.22 micron low protein binding polyethersulfone (PES) in-line infusion filter. Use infusion sets and lines that are di(2-ethylhexyl)phthalate-free (DEHP-free)
- 0.9% Sodium Chloride Injection, USP (normal saline solution) infusion bag

Additional equipment and supplies will be needed based on individual patient needs.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Fractures

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ADVERSE REACTIONS

The most common adverse reactions (incidence $\geq 20\%$ of patients treated with ISEMBYLD and more frequent than placebo) were upper respiratory tract infections, vomiting, cough, other viral infections, headache, gastroenteritis, pharyngitis, and hypersensitivity.

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Weight-Based Dosing

Dosing for ISEMBYLD is calculated by weight.
The recommended dose is 10 mg/kg administered once every 4 weeks over approximately 1-2 hours at an infusion rate no greater than 150 mL/hour.¹

Included below are sample calculations for an individual weighing 30 kg (1 kg = 2.2 lbs).

Calculating Dose Volume

Weight
(kg)

×

Recommended
Dose (10 mg/kg)

=

Total Dose
(mg)

Example for an individual weighing 30 kg: 30 kg x 10 mg/kg = 300 mg

Calculating Number of Vials

Total Dose
(mg)

÷

Amount of 1 Vial
(150 mg)

=

Total Vials
Needed

Example for an individual weighing 30 kg: 300 mg / 150 mg = 2 vials

Calculating Volume to Withdraw

Total Dose
(mg)

÷

50 mg/mL
(Each mL
contains 50 mg)

=

Volume to
Withdraw (mL)

Example for an individual weighing 30 kg: 300 mg / 50 mg/mL = 6 mL to withdraw

Calculating Total Infusion Volume

Total Dose
(mg)

÷

5 mg/mL

=

Total Volume of
Infusion (mL)

Example for an individual weighing 30 kg: 300 mg / 5 mg/mL = 60 mL

Calculating Total Saline Volume

Total Infusion
Volume (mL)

—

Total Volume to
Withdraw (mL)

=

Total Saline
Volume (mL)

Example for an individual weighing 30 kg: 60 mL - 6 mL = 54 mL

IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS

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There are no data on the presence of ISEMBYLD in human milk, the effects on the breastfed infant, or the effects of the drug on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for ISEMBYLD, and any potential adverse effects on the breastfed infant.

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Dosing Chart

Not all patient weights are included in the chart below. This is not meant to replace calculating the exact dose and number of vials needed for each individual patient.

Weight (kg)	Calculated Dose (10 mg/kg)	Number of Vials (150 mg/3 mL [50 mg/mL])	Required Volume to Withdraw (mL)	Saline Volume (mL)	Total Infusion Volume (mL)
5	50	1	1.0	9.0	10
6	60	1	1.2	10.8	12
7	70	1	1.4	12.6	14
8	80	1	1.6	14.4	16
9	90	1	1.8	16.2	18
10	100	1	2.0	18.0	20
11	110	1	2.2	19.8	22
12	120	1	2.4	21.6	24
13	130	1	2.6	23.4	26
14	140	1	2.8	25.2	28
15	150	1	3.0	27.0	30
16	160	2	3.2	28.8	32
17	170	2	3.4	30.6	34
18	180	2	3.6	32.4	36
19	190	2	3.8	34.2	38
20	200	2	4.0	36.0	40
21	210	2	4.2	37.8	42
22	220	2	4.4	39.6	44
23	230	2	4.6	41.4	46
24	240	2	4.8	43.2	48
25	250	2	5.0	45.0	50
26	260	2	5.2	46.8	52
27	270	2	5.4	48.6	54
28	280	2	5.6	50.4	56
29	290	2	5.8	52.2	58
30	300	2	6.0	54.0	60
31	310	3	6.2	55.8	62
32	320	3	6.4	57.6	64
33	330	3	6.6	59.4	66
34	340	3	6.8	61.2	68
35	350	3	7.0	63.0	70
36	360	3	7.2	64.8	72
37	370	3	7.4	66.6	74
38	380	3	7.6	68.4	76
39	390	3	7.8	70.2	78
40	400	3	8.0	72.0	80
41	410	3	8.2	73.8	82
42	420	3	8.4	75.6	84
43	430	3	8.6	77.4	86
44	440	3	8.8	79.2	88
45	450	3	9.0	81.0	90
46	460	4	9.2	82.8	92
47	470	4	9.4	84.6	94
48	480	4	9.6	86.4	96
49	490	4	9.8	88.2	98
50	500	4	10.0	90.0	100
51	510	4	10.2	91.8	102
52	520	4	10.4	93.6	104
53	530	4	10.6	95.4	106
54	540	4	10.8	97.2	108
55	550	4	11.0	99.0	110
56	560	4	11.2	100.8	112
57	570	4	11.4	102.6	114
58	580	4	11.6	104.4	116
59	590	4	11.8	106.2	118
60	600	4	12.0	108.0	120
61	610	5	12.2	109.8	122
62	620	5	12.4	111.6	124
63	630	5	12.6	113.4	126
64	640	5	12.8	115.2	128
65	650	5	13.0	117.0	130
66	660	5	13.2	118.8	132
67	670	5	13.4	120.6	134
68	680	5	13.6	122.4	136
69	690	5	13.8	124.2	138
70	700	5	14.0	126.0	140

IMPORTANT SAFETY INFORMATION

Females and Males of Reproductive Potential

Based on animal data, ISEMBYLD may affect male and/or female reproductive function.

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

Recommendations Regarding Missed Dose¹

If a planned dose is missed, it is recommended to administer ISEMBYLD as soon as possible and then restart the dosing schedule 4 weeks after the missed dose is administered.

Alternatively, if a planned dose is missed, dosing may be resumed on the next scheduled dose to maintain the original dosing schedule.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Fractures

ISEMBYLD may increase the risk of fractures, including serious fractures. Use with caution in patients with a history of low bone density or multiple fractures. In patients who experience fractures, weigh the risks and benefits of continuing ISEMBYLD.

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Preparing ISEMBYLD¹

ISEMBYLD must be diluted in 0.9% Sodium Chloride Injection to a final concentration of 5 mg/mL prior to intravenous infusion. **The diluted solution for infusion must be prepared by a healthcare professional using aseptic technique as follows:**

- 1 Calculate the required dose (mg) of ISEMBYLD to be administered based on the patient's weight and on the recommended dosage of 10 mg/kg. Determine the volume (mL) of ISEMBYLD needed and the correct number of vials to supply the calculated dose.
- 2 Remove ISEMBYLD vials from the refrigerator and allow vials to warm to room temperature while remaining in the carton until time of use. **Do not use external heat sources to warm ISEMBYLD vials because heat may damage the product. Do not shake.**
- 3 Visually inspect each vial of ISEMBYLD. ISEMBYLD is a clear to moderately opalescent, colorless to slightly yellow solution that is free from visible particulates. **Do not use if the solution in the vial is discolored or particulate matter is present.**
- 4 Withdraw the required volume of ISEMBYLD from each vial using a sterile syringe and transfer to an infusion bag that is di(2-ethylhexyl)phthalate-free (DEHP-free).
- 5 Dilute ISEMBYLD to a final concentration of 5 mg/mL by adding the appropriate amount of 0.9% Sodium Chloride Injection to the infusion bag.
- 6 Gently invert the bag to mix the solution. **Do not shake. Do not mix or dilute with other drugs.**
- 7 Discard any unused ISEMBYLD remaining in the vial(s).
- 8 The diluted solution should be administered immediately after preparation. If not used immediately, store the infusion bag, protected from light, either at room temperature (20°C to 25°C [68°F to 77°F]) or in a refrigerator at 2°C to 8°C (36°F to 46°F) for up to 4 hours (including preparation and infusion time). **Do not freeze.**

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥20% of patients treated with ISEMBYLD and more frequent than placebo) were upper respiratory tract infections, vomiting, cough, other viral infections, headache, gastroenteritis, pharyngitis, and hypersensitivity.

Please see additional Important Safety Information throughout and full [Prescribing Information](#).

Infusing ISEMBYLD¹

ISEMBYLD can be administered as an IV infusion in a hospital, at home, or at an infusion center.

- 1** If necessary, remove the diluted ISEMBYLD solution from the refrigerator and allow the diluted solution to warm to room temperature. Do not use external heat sources to warm ISEMBYLD diluted solution because heat may damage the product.
- 2** Visually inspect the diluted ISEMBYLD solution for particles or discoloration prior to administration. *[see Dosage Forms and Strengths (3)]*. Do not use if it is discolored, opaque, or foreign particles are seen.
- 3** Use a dedicated line with an infusion set containing a 0.2 or 0.22 micron low protein binding polyethersulfone (PES) in-line infusion filter. Use infusion sets and lines that are di(2-ethylhexyl)phthalate (DEHP)-free.
- 4** Infuse the diluted solution of ISEMBYLD intravenously over approximately 1-2 hours at an infusion rate of no greater than 150 mL/hour.
- 5** After completion of the infusion, flush the infusion line with 0.9% Sodium Chloride Injection to ensure that all the ISEMBYLD has been administered.

To report suspected adverse reactions, contact Scholar Rock, Inc., at 1-855-MED-SRRK or medicalinformation@scholarrock.com, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS

Pregnancy and Lactation

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Females and Males of Reproductive Potential

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Scholar Rock Supports™ offers personalized support for your patients' ISEMBYLD journey

Scholar Rock Supports™ is designed to help your patients get access to ISEMBYLD and to provide support throughout the treatment experience.

Scholar Rock Supports™ includes **Rx Onboarding and Care Coordinators (ROCCs)**, Case Managers, and a full suite of support programs.

The dedicated ROCCs can help patients and caregivers with:

- Navigating insurance
- Financial and copay assistance (for eligible patients)
- Infusion day logistics
- Caregiver support
- Educational materials
- What to expect with ISEMBYLD

**To learn more, call Scholar Rock Supports™ at 877-473-6295
Monday – Friday 8 AM – 8 PM ET**

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INDICATION

ISEMBYLD is indicated for the treatment of spinal muscular atrophy (SMA) in adults and pediatric patients 2 years of age and older who are currently receiving a survival motor neuron 2 (SMN2)-targeted treatment.

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Females and Males of Reproductive Potential

Based on animal data, ISEMBYLD may affect male and/or female reproductive function.

Please see full [Prescribing Information](#).

Indicated for the treatment of SMA in adults and pediatric patients 2 years of age and older who are currently receiving an SMN2-targeted treatment¹

ISEMBYLD is administered by a healthcare professional in a hospital, at home, or at an infusion center¹



Weight-based dosing



One infusion every 4 weeks



Administered over ~1-2 hours

VISIT [ISEMBYLDHCP.COM](https://www.iseatsbyldhcp.com) TO DISCOVER MORE ABOUT ISEMBYLD

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

SMA=spinal muscular atrophy, SMN2=survival motor neuron 2.

References: 1. ISEMBYLD. Prescribing information. Scholar Rock, Inc; 2026. 2. Data on file. Scholar Rock, Inc. Cambridge, MA.