

INSTRUCTIONS FOR USE
ZANVASTRO™ [zan-VASS-troh]
(zilganersen) injection
for intrathecal use

This Instructions for Use is intended for healthcare professionals and contains instructions for preparing ZANVASTRO™ for intrathecal administration. Read this entire Instructions for Use before diluting and preparing ZANVASTRO.

Important information:

- Each carton contains 1 vial of ZANVASTRO and 1 vial of diluent to be used together to prepare a single dose. The final dose volume of the intrathecal injection is determined by the patient's age.
- The diluent vial contains more volume than needed. Discard excess diluent prior to dilution as instructed in the preparation steps below.
- Always use aseptic technique when preparing and administering ZANVASTRO.
- Do not use if expiration date has passed.
- Do not use vials if solution is cloudy, discolored, or contains particles.
- Do not use if vials or carton are damaged.

Storing ZANVASTRO:

- Store the ZANVASTRO vial and diluent vial in the refrigerator between 2°C and 8°C (36°F and 46°F) in the original carton to protect from light. The ZANVASTRO vial and diluent vial can be stored at room temperature up to 30°C (86°F) in the original carton for up to 14 days.
- Do not freeze. Do not expose to heat.
- See Step 7 below for storage of the prepared diluted dosing syringe.

Carton contents:

- One vial of ZANVASTRO, 56 mg/2.8 mL (20 mg/mL)
- One vial of artificial cerebrospinal fluid (aCSF) diluent, 21 mL

Other recommended supplies for dose preparation (not included in carton):

- 3 mL and/or 10 mL syringe(s) to withdraw excess diluent
- One 3 mL syringe to draw up ZANVASTRO
- Two to three 18G to 22G needles (three needles will be required for patients under 2 years of age)
- One 18G or 19G filter needle (5 micron)
- One 20 mL syringe
- One 20 mL syringe tip cap

Step 1 Withdraw and discard excess aCSF diluent based on patient's age

- a) Determine the volume of excess aCSF diluent to withdraw from the diluent vial using the patient's age and [Table 1](#) below.
- b) Prepare syringe(s) with an 18G to 22G needle based on the volume of diluent to be removed (3 mL and/or 10 mL syringe recommended).
- c) Withdraw the excess diluent from the diluent vial.
- d) Keep the diluent vial containing the remaining diluent. You will need it for Step 3.
- e) Discard the syringe(s) containing the excess diluent in a sharps container.

Step 2 Withdraw ZANVASTRO

- a) Prepare a new 3 mL syringe with a new 18G to 22G needle.
- b) Withdraw 2.8 mL of ZANVASTRO from the ZANVASTRO vial.

Step 3 Add ZANVASTRO to the remaining diluent in the diluent vial

- a) Add the withdrawn ZANVASTRO to the diluent vial.
- b) Dispose of the syringe and ZANVASTRO vial in a sharps container. Some residual medicine may remain in the ZANVASTRO vial.

Step 4 Mix

Gently invert the diluent vial (which now also contains ZANVASTRO) several times to mix the solution.

Step 5 Withdraw dose volume based on patient's age

- a) Attach an 18G or 19G filter needle to a 20 mL syringe.
- b) Withdraw the recommended dose volume of diluted ZANVASTRO from the diluent vial as determined by [Table 1](#) below based on the patient's age.

Step 6 Prepare the dosing syringe

- a) Remove the filter needle and attach a syringe tip cap to the prepared dosing syringe.
- b) Dispose of diluent vial and filter needle in a sharps container.
Some residual solution might be in the vial after dose volume is withdrawn.

Step 7 Label the prepared dosing syringe

- a) Label the prepared dosing syringe per institution procedures prior to use or transport.
- b) ZANVASTRO contains no preservatives. The dose must be administered within:
 - 4 hours of preparation if kept at room temperature up to 30°C (86°F).
 - 24 hours of preparation if refrigerated at 2°C to 8°C (36°F to 46°F).
 - Do not freeze. Do not expose to heat.
 - Protect the prepared dosing syringe from light as a precaution.

Table 1: ZANVASTRO Dilution Procedures

Patient age	Volume of excess aCSF diluent to withdraw from the diluent vial and discard	Volume of ZANVASTRO to add to the diluent vial	Volume of diluted Zanzastro to withdraw from the diluent vial for administration (Dose volume)
Less than 2 years old	12.6 mL	2.8 mL	10 mL
2 years old to 7 years old (inclusive)	7 mL	2.8 mL	15 mL
8 years old and above	1.4 mL	2.8 mL	20 mL

Refer to the Prescribing Information for administration instructions.

For more information, go to <https://www.ZANVASTRO.com> or call 1-833-644-6647.

Distributed by: Ionis Pharmaceuticals, Inc., Carlsbad, CA 92010

This Instructions for Use has been approved by the U.S. Food and Drug Administration

Revised: 09/2026