Givosiran: Stability in Prepared Syringe

The following information is provided in response to your unsolicited inquiry. It is intended to provide you with a review of the available scientific literature and to assist you in forming your own conclusions in order to make healthcare decisions. This document is not for further dissemination or publication without authorization.

The full Prescribing Information for GIVLAARI[®] (givosiran) is provided <u>here</u>. Alnylam Pharmaceuticals does not recommend the use of its products in any manner that is inconsistent with the approved Prescribing Information. This resource may contain information that is not in the approved Prescribing Information.

If you are seeking additional scientific information related to Alnylam medicines, you may visit the Alnylam US Medical Affairs website at <u>RNAiScience.com</u>.

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Label Information – References

GIVLAARI US PRESCRIBING INFORMATION – RELEVENT CONTENT

The DOSAGE AND ADMINISTRATION section provides the following information¹:

Administration Instructions

Ensure that medical support is available to appropriately manage anaphylactic reactions when administering GIVLAARI.

GIVLAARI is intended for subcutaneous use by a healthcare professional only.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. GIVLAARI is a sterile, preservative-free, clear, colorless-to-yellow solution. It is supplied in a single-dose vial, as a ready-to-use solution that does not require additional reconstitution or dilution prior to administration.

Use aseptic technique.

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- Calculate the required volume of GIVLAARI based on the recommended weight-based dosage.
 - Withdraw the indicated injection volume of GIVLAARI using a 21-gauge or larger needle. O Divide doses requiring volumes greater than 1.5 mL equally into multiple syringes.
- *Replace the 21-gauge or larger needle with either a 25-gauge or 27-gauge needle with 1/2" or 5/8" needle length.*
- Avoid having GIVLAARI on the needle tip until the needle is in the subcutaneous space.
- Administer injection into the abdomen, the back or side of the upper arms, or the thighs. Rotate injection sites. An injection should never be given into scar tissue or areas that are reddened, inflamed, or swollen.
 - If injecting into the abdomen, avoid a 5 cm diameter circle around the navel.
 - If more than one injection is needed for a single dose of GIVLAARI, the injection sites should be at least 2 cm apart from previous injection locations.
- Discard unused portion of the drug.

The HOW SUPPLIED/STORAGE AND HANDLING section provides the following information¹: <u>Storage and Handling</u> Store at $2^{\circ}C$ to $25^{\circ}C$ ($36^{\circ}F$ to $77^{\circ}F$).

Store GIVLAARI in its original container until ready for use.

Updated 13 January 2025

REFERENCES

1. GIVLAARI (givosiran) Prescribing Information. Cambridge, MA: Alnylam Pharmaceuticals, Inc.