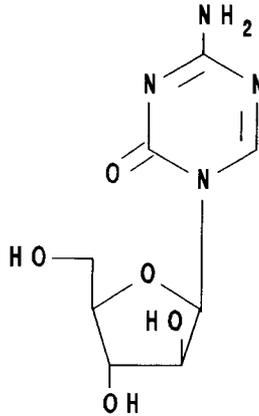


FAZARABINE

NSC - 281272



Chemical Name: 4-Amino-1- β -D-arabinofuranosyl-1,3,5-triazin-2(1H)-one

Other Names: Ara-AC; 5-Azacytosine arabinoside, Fazarabine (USAN)

CAS Registry Number: 65886-71-7

Molecular Formula: C₈H₁₂N₄O₅

M.W.: 244.2

How Supplied: Sterile, 250 mg, vial: supplied as a white lyophilized powder in a 60 mL flint vial. Fazarabine for infusion in aqueous solutions (3 hours or less) is labeled differently from fazarabine for infusion in DMSO, but the products are identical.

Solution Preparation: The drug is prepared using one of the two following preparation methods:

1. Aqueous preparation:

Constitute the 250 mg vial with 25 mL of Sterile Water for Injection, USP, to yield a 10 mg/mL solution. Immediately further dilute the dose in a suitable quantity of Lactated Ringer's Injection, USP, to yield a fazarabine concentration of between 0.01 and 1 mg/mL. Because of fazarabine's rapid decomposition, infusions must be completed in three hours or less.

Note: Older aqueous labels used 10 mL constitution volumes to give a 25 mg/mL concentration. This concentration takes up to ten minutes to achieve with vigorous shaking . Since the product is further diluted anyway the 25 mL addition of Sterile Water achieves complete solution within three minutes.

2. DMSO preparation:

Constitute the 250 mg vial with 3.5 mL of sterile 70% (v/v) dimethylsulfoxide (DMSO) NSC - 763 to yield a 70 mg/mL solution. Further dilute according to protocol instructions with additional sterile 70% DMSO to yield the appropriate fazarabine concentration. This solution is to be administered slowly into a running intravenous infusion of 5% Dextrose Injection, USP, via a side injection port using a syringe pump. A total volume of 12 mL with an infusion rate of 0.5 mL/hour is suggested for the fazarabine in 70% DMSO solution.

NOTE: It is recommended that the accuracy of the syringe pump delivery rate be verified (using sterile water for injection or other aqueous solution) prior to drug administration.

This administration approach was developed by Dr. A. J. Repta and associates at the University of Kansas. For additional information see their published article: Mojaverian P and Repta AJ: J Pharmacy Pharmacol 36: 728-733, 1984.

Storage: Store the intact vials under refrigeration (2-8 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing. The intact vials are stable for at least 4 years at room temperature (22-25 °C). The intact vials are stable for at least one year when stored at elevated temperature (50 °C).

Constitution of fazarabine with 10 mL of Sterile Water for Injection, USP, and further dilution to a final concentration between 0.01 and 1 mg/mL in Lactated Ringer's Injection, USP, results in a solution which exhibits approximately 10% decomposition in three hours at room temperature. Consequently, infusion of solutions prepared in this manner should be completed within three hours of admixture.

Fazarabine constituted and further diluted with 70% DMSO is more stable. At fazarabine concentrations ranging from 2 to 70 mg/mL, the drug exhibits approximately 10% loss in 24 hours at room temperature.

NOTE: To minimize the extraction of plasticizer from polyvinyl chloride (PVC) I.V. tubing by DMSO solvent, use of sterile microbore tubing with an inner lining of polyolefin is recommended for connecting the syringe pump to the side port of the running 5% Dextrose Injection, USP, infusion. A tubing known to be satisfactory is the Polyfin® extension set supplied by Mini Med Technologies (12744 San Fernando Road, Sylmar, CA 91342. Telephone: 800-933-3322 in California.)

Route of Administration: Intravenous