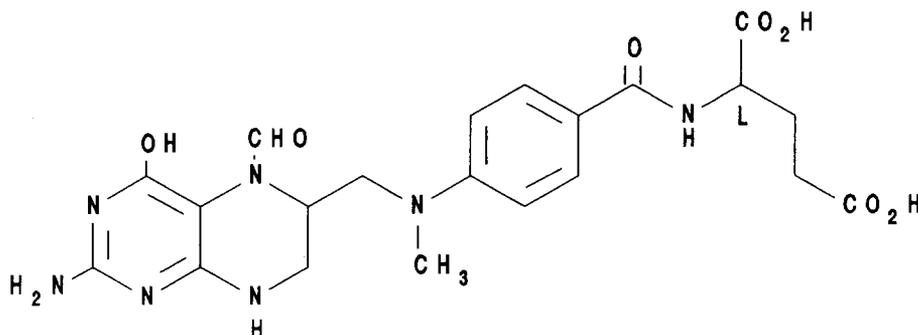


LEUCOVORIN CALCIUM

NSC - 3590



Chemical Name: N-[4-[[2-Amino-5-formyl-1,4,5,6,7,8-hexahydro-4-oxo-6-pteridinyloxy)methyl]amino]benzoyl]-L-glutamic acid, calcium salt (1:1), (R,S)-

Other Names: Citrovorum Factor, Folinic Acid, Leucosar[®], Wellcovorin[®], Leucovorin Calcium (USAN)

CAS Registry Number: 1492-18-8

Molecular Formula: C₂₀H₂₅N₇O₇ · Ca **M.W.:** 511.5

How Supplied: For Injection, 50 mg (leucovorin equivalent present as calcium salt), vial, with sodium chloride, 45 mg. The product is prepared as a pale-yellow lyophilized powder in 10 mL flint vials.

For Injection, 500 mg (leucovorin equivalent present as calcium salt), vial, with sodium chloride, 80 mg. The product is prepared as a pale-yellow lyophilized powder in 30 mL flint vials.

Solution Preparation: 50 mg/vial: When constituted with 5 mL of Sterile Water for Injection, USP, each milliliter contains leucovorin calcium equivalent to leucovorin 10 mg and sodium chloride 9 mg. The pH of the solution is 6.0 to 8.0.

500 mg/vial : When constituted with 9.7 mL of Sterile Water for Injection, USP, each milliliter contains leucovorin calcium equivalent to leucovorin 50 mg and sodium chloride 8 mg. The pH of the solution is 6.5 to 8.5.

Storage: Store the intact vials at room temperature.

Stability: The intact vials are stable up to the expiration date when stored at room temperature (22-25 °C). Shelf-life studies on the 500 mg dosage form are ongoing.

Constitution as directed results in a solution which is chemically stable for at least 7 days at room temperature.

CAUTION: It is advised that the vials constituted with Sterile Water for Injection, USP, be discarded within 8 hours of initial entry.

Route of Administration: Intramuscular, intravenous, oral