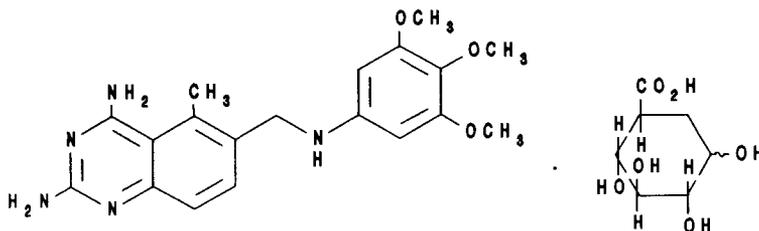


# TRIMETREXATE

NSC - 352122

The product described below is supplied by Warner-Lambert Company, Ann Arbor, Michigan, for clinical trials sponsored by the Division of Cancer Treatment, National Cancer Institute.



**Chemical Name:** 6-(((3,4,5-trimethoxyphenyl)amino)methyl)-5-methyl-2,4-quinazolinediamine, D-glucuronic acid

**Other Names:** TMTX, Trimetrexate (USAN)

**CAS Registry Number:** 52128-35-5

**Molecular Formula:**  $C_{19}H_{23}N_5O_3 \cdot C_6H_{10}O_7$       **M.W.:** 564.0

**How Supplied:** For injection, 25 mg, vial: supplied as a pale greenish-yellow to tan colored lyophilized powder with glucuronic acid to form the glucuronate salt, in 6 mL flint vials.

**Solution Preparation:** 25 mg/vial: When constituted with 2 mL of Sterile Water for Injection, USP, each milliliter contains 12.5 mg of trimetrexate, present as the glucuronate salt. The pH of the constituted solution is 3.5 to 5.5.

**Storage:** Store the intact vials at room temperature.

**Stability:** Shelf-life surveillance of the intact vials is ongoing. Evaluation by Warner-Lambert has shown that trimetrexate is stable for at least 24 months at room temperature (22-25 °C).

When constituted as directed, the solution of trimetrexate is stable for up to 24 hours both at room temperature (22-25 °C) and under refrigeration (2-8 °C).

Further dilution to a concentration of 0.1 mg/mL in 5% Dextrose Injection, USP, results in a solution in which trimetrexate is stable both at room temperature and under refrigeration for at least 48 hours. At a concentration of 4 mg/mL in 5% Dextrose Injection, USP, trimetrexate is stable for 24 hours at room temperature or under refrigeration.

Exposure of both the constituted solution and the admixture in 5% Dextrose Injection, USP, to normal laboratory light during room temperature storage did not affect the stability of trimetrexate.

Trimetrexate may develop a precipitate in solutions above pH 5.

**CAUTION:** The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

**NOTE:** Trimetrexate is incompatible with Sodium Chloride Injection, USP, and other chloride-containing solutions. Admixture with these solutions may result in precipitate formation.

**Route of Administration:** Intravenous