Leucovorin Calcium for Injection

**DESCRIPTION**

Leucovorin calcium is a mixture of the d (+)-isomer of 5,6,7,8-tetrahydrofolic acid (THF) and the L (+)-isomer of 5-formyl-5,6,7,8-tetrahydrofolic acid (THF). The biologically active component of the mixture is 5,6,7,8-tetrahydrofolic acid (THF). The biologically active compound of the mixture is 5,6,7,8-tetrahydrofolic acid (THF). The major component of the mixture is 5-methyltetrahydrofolate. The minor component is 5-formyltetrahydrofolate. The l-dose of leucovorin calcium contains 0.002 mmol of calcium. Each 350 mg vial of Leucovorin Calcium for Injection, when reconstituted with 5 mL of sterile diluent, contains leucovorin (as the calcium salt) 10 mg/mL.

**INDICATION AND USES**

Leucovorin calcium is a product that is available for intramuscular (IM) or intravenous (IV) administration and is supplied in 50 mg, 100 mg, 200 mg, and 500 mg vials.

**Dosage and Administration**

Leucovorin calcium rescue is indicated after high dose methotrexate therapy in celiac disease. Leucovorin calcium is also indicated to delay the onset of and to treat the effects of impaired folic acid utilization and/or reduction of folic acid antagonists.

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**WARNINGS**

**Delayed methotrexate excretion may be caused by a third space fluid accumulation (i.e., sepsis, pleural effusion, renal insufficiency, inadquate fluid intake), which may require longer intravenous leucovorin administration.**

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**Toxicity decreases. In the treatment of accidental overdosages of intrathecally administered methotrexate, intravenous leucovorin should be administered as promptly as possible. As the time interval between antifolate administration (e.g., methotrexate) and leucovorin administration is increased, toxicity decreases.**

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**In the event of accidental overdosage of folate antagonists, intravenous leucovorin calcium should be administered immediately even if there is no evidence of toxicity, since its effects are dose related.**

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**PRECAUTIONS**

**Patients being treated with the leucovorin/5-fluorouracil combination should be monitored closely for diarrhoea.**

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Bioavailability of leucovorin is less than 10^{-8} M. In the presence of gastrointestinal toxicity, nausea, or vomiting, leucovorin should be administered parenterally. Do not administer leucovorin intrathecally.

Folic acid antagonists.

Excessive amounts of leucovorin may nullify the chemotherapeutic effect of 5-fluorouracil (see WARNINGS). DO NOT ADMINISTER LEUCOVORIN INTRATHECALLY.

To report SUSPECTED ADVERSE REACTIONS, contact Sagent Pharmaceuticals, Inc. at 1-866-625-1618 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.