WARNINGS
Folic acid in large amounts may counteract the antiepileptic effect of phenobarbital, phenytoin and valproate. However, because the folic acid supplement may be of benefit in the management of the patient's anticonvulsant therapy, the decision to use folic acid should be made on an individual basis.

DOSAGE AND ADMINISTRATION
Leucovorin is improper therapy for pernicious anemia and other megaloblastic anemias secondary to vitamin B12 deficiency. Leucovorin is also indicated for use in combination with 5-fluorouracil to prolong survival in the metastatic colon cancer patient. Prior to initiating leucovorin therapy in the treatment of colorectal cancer, serum methotrexate levels should be determined if the patient has received the 3-drug regimen. Serum methotrexate levels should be obtained before each treatment cycle to ensure that the leucovorin dose is adequate to reverse methotrexate toxicity. Treatment cycles should be repeated every 4 to 6 weeks. Leucovorin may be used with or without 5-fluorouracil. Leucovorin therapy must be initiated before administration of 5-fluorouracil.

INDICATIONS AND USAGE
In combination with 5-fluorouracil, leucovorin calcium is indicated to diminish the toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdosages of folic acid antagonists. Leucovorin calcium is also indicated to diminish the toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdosages of folic acid antagonists.

Drug Interactions
When leucovorin is administered with folate antagonist chemotherapy, the incidence and severity of toxicity is usually increased.

DIAGNOSIS
Neutrophil and platelet counts should be obtained prior to and at intervals during leucovorin therapy. If blood counts do not reach these levels within two weeks, leucovorin therapy should be discontinued.

NURSING MOTHERS
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when leucovorin is administered to a nursing woman.

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Note: This is a computer-generated summary of a U.S. product label. For the most current and complete product labeling, please consult the full prescribing information provided by the manufacturer.

This summary is intended for use as a resource by health care professionals. This summary is not a guide to self-medication. Patients should consult their health care provider for individual advice about specific conditions.

Note: The reference material, including the full prescribing information, may be accessed via the link provided in the footnotes.

Store at refrigerator 2° to 8°C (36° to 46°F). Protect from light. Discard unused portion. Retain in
HOW SUPPLIED

formation of a precipitate.

Leucovorin should not be mixed in the same infusion as 5-fluorouracil, since this may lead to the

Parenteral products should be inspected visually for particulate matter and discoloration prior to

exceeds 1 mg.

concomitantly. The bicarbonate dose should be adjusted to maintain the urine pH at 7.0 or greater.

100 mg/m²

than 10

10 mg/m²

hours of methotrexate administration when there is delayed excretion (see

Leucovorin rescue should begin as soon as possible after an inadvertent overdosage and within 24

Impaired Methotrexate Elimination or Inadvertent Overdosage

these abnormalities may or may not be associated with significant clinical toxicity. If

methotrexate administration, which are significant but less severe than abnormalities described in the

urinary alkalization, and close monitoring of fluid and electrolyte status, until the serum methotrexate

Serum creatinine and methotrexate levels should be determined at least once daily. Leucovorin

administered by intravenous infusion over 4 hours (see methotrexate package insert for full prescribing

The recommendations for leucovorin rescue are based on a methotrexate dose of 12 to 15 grams/m²

Leucovorin Rescue After High-Dose Methotrexate Therapy

Tests

for patients who experienced moderate hematologic or gastrointestinal toxicity in the prior treatment

(28-day) intervals, for 2 courses and then repeated at 4 to 5 week (28 to 35 day) intervals provided that

Treatment is repeated daily for five days. This five-day treatment course may be repeated at 4 week

5-Fluorouracil and leucovorin should be administered separately to avoid the formation of a precipitate.

Either of the following two regimens is recommended:

1. Leucovorin is administered at 200 mg/m² followed by 5-fluorouracil at 370 mg/m²

2. Leucovorin is administered at 20 mg/m²

followed by 5-fluorouracil at 370 mg/m²

Table 1 summarizes significant adverse events occurring in 316 patients treated with the leucovorin/5-

administration of both oral and parenteral leucovorin. No other adverse reactions have been attributed to

PRECAUTIONS: Laboratory

M or the 48 hour level is greater than 9 x 10⁻⁸. The leucovorin dose should be adjusted or

in 1 CARTON

HYDROCHLORIC ACID

SODIUM HYDROXIDE

(UNII: Q573I9DVLP)

LEUCOVORIN

Pharmaceuticals GmbH

Ingenus Pharmaceuticals, LLC

Ingenus Pharmaceuticals, LLC (833250017)

Marketing Category

Product Information

Application Number or Monograph Citation

Marketing End Date

Item Code

Package Description

Name

ID/FEI

Marketing End

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