

THE INFORMATION FOR THE CONSUMER

Lederle LEUCOVORIN calcium folinate tablets

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Lederle Leucovorin Calcium. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

The medication is used -

- a) To diminish the toxicity and counteract the effect of impaired METHOTREXATE elimination.
- b) To treat the megaloblastic anemias due to folate deficiency, as in sprue, nutritional deficiency, megaloblastic anemias of pregnancy and infancy.

What it does:

LEUCOVORIN is a reduced form of folic acid. LEUCOVORIN limits METHOTREXATE action on normal cells by competing with METHOTREXATE for the same transport processes into the cell. LEUCOVORIN rescues bone marrow and gastrointestinal cells from METHOTREXATE but has no apparent effect on pre-existing METHOTREXATE nephrotoxicity.

When it should not be used:

Do not take LEUCOVORIN

- if you are allergic (hypersensitive) to calcium folinate or any of the other ingredients of LEUCOVORIN OR
- If you have megaloblastic anaemia due to Vitamin B₁₂ deficiency

What the medicinal ingredient is:

LEUCOVORIN Calcium (also known as calcium folinate).

What the important nonmedicinal ingredients are:

Non-medicinal ingredients are: Lactose, Magnesium Stearate, Microcrystalline Cellulose, Sodium Starch Glycolate and Starch Pregelatinized 1500.

What dosage forms it comes in:

Tablet: 5 mg LEUCOVORIN as LEUCOVORIN calcium

WARNINGS AND PRECAUTIONS

In very rare cases sloughing of the skin, rarely leading to death, has been reported in patients receiving Leucovorin along with other medications known to have similar side-effects.

Leucovorin should only be used under the direct supervision of a clinician experienced in the use of cancer chemotherapeutic agents.

BEFORE you use LEUCOVORIN talk to your doctor or pharmacist if:

- You have symptoms of gastrointestinal disorders.
- You are taking cytotoxic drugs (hydroxycarbamide, cytarabine, mercaptopurine, thioguanine).
- You are epileptic and are being treated with phenobarbital, primidone, phenytoin and succinimides.
- If you are Pregnant or Nursing.

INTERACTIONS WITH THIS MEDICATION

LEUCOVORIN can interfere with the breakdown or metabolism of certain drugs. In particular, you should inform your doctor if you are taking any of the following:

- Cytotoxic drugs - 5-fluorouracil (5FU), Methotrexate (High doses of LEUCOVORIN may reduce the efficacy of Methotrexate. LEUCOVORIN may enhance the toxicity of fluorouracil.)
- Folic acid antagonists – cotrimxazole, pyrimethamine
- Anti-epileptic substances - phenobarbital, primidone, phenytoin and succinimides.

PROPER USE OF THIS MEDICATION

Usual dose:

Take your dose as prescribed by the physician.

Overdose:

If you take too much LEUCOVORIN (Overdose):

- Immediately call your doctor or go to the nearest hospital emergency department
- Do this even if you have no signs of discomfort
- Always take the labelled medicine bottle with you, even if it is empty

Missed Dose:

Not Applicable.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Undesirable effects have been rarely reported.

Allergic sensitization, including anaphylactoid/anaphylactic reactions (including shock) and urticaria, has been reported following administration of folinic acid.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	<ul style="list-style-type: none"> ▪ Nausea, ▪ Vomiting, ▪ Diarrhea 		<ul style="list-style-type: none"> ✓ ✓ ✓ 	
Uncommon	<ul style="list-style-type: none"> ▪ Allergic reactions ▪ Any skin disorders 		<ul style="list-style-type: none"> ✓ ✓ 	
Rare	<ul style="list-style-type: none"> ▪ Seizures /syncope (<i>Fainting / Dizziness</i>) 		<ul style="list-style-type: none"> ✓ 	
Very Rare	<ul style="list-style-type: none"> ▪ Anaphylactoid / anaphylactic reactions (including shock) 		<ul style="list-style-type: none"> ✓ 	
Frequency undetermined	<ul style="list-style-type: none"> ▪ Allergic reactions, urticaria ▪ Fever ▪ Palmar-Plantar Erythrodysesthesia (<i>Hand and Foot Syndrome</i>) ▪ Mucositis (<i>mouth ulcers</i>) ▪ Stomatitis (<i>mouth ulcers</i>) ▪ Chelitis (<i>swelling of the lip</i>) ▪ Hyperammonemia (excess ammonia in the blood) 		<ul style="list-style-type: none"> ✓ ✓ ✓ ✓ ✓ ✓ ✓ 	

This is not a complete list of side effects. For any unexpected effects while taking LEUCOVORIN, contact your doctor or pharmacist.

HOW TO STORE IT

Tablets should be stored at 15-30°C. Protect from light.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax 866-678-6789

By email: cadmp@hc-sc.gc.ca

By regular mail:

National AR Centre

Marketed Health Products Safety and Effectiveness Information Division

Marketed Health Products Directorate

Tunney's Pasture, AL 0701C

Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, Wyeth Canada, at: 1-800-461-8844.

This leaflet was prepared by Wyeth Canada

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