

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^{Pf}LEUCOVORIN CALCIUM INJECTION USP

Leucovorin calcium

Read this carefully before you receive **Leucovorin Calcium Injection USP**. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Leucovorin Calcium Injection USP**.

Serious Warnings and Precautions

- You will receive Leucovorin Calcium Injection USP:
 - as a shot into your muscle (intramuscularly) or as a shot or infusion (drip) into your vein (intravenously). It must not be given into the fluid-filled space between the thin layers of tissue that cover the brain and spinal cord (intrathecally). Deaths have happened in people getting this medicine into the spine.
 - with 5-fluorouracil or methotrexate only under the care of a healthcare professional experienced in the use of anti-cancer medicines.
- If you are receiving leucovorin with fluorouracil (an anticancer medicine), your healthcare professional will monitor you for side effects like diarrhea or painful sores that may make it hard for you to eat, drink, or swallow (stomatitis/mucositis). These are early signs of severe and potentially life-threatening side effects. Talk to your healthcare professional **right away** if you experience any of these side effects.
- Deaths from the following side effects have happened in people getting leucovorin:
 - **Severe problems with the digestive system** (gastrointestinal toxicity): These include diarrhea and mucositis (ulcers (open sores) and swelling of lining of the bowels and mouth).
 - **Severe drop in blood cell counts** (myelosuppression, a condition in which the bone marrow cannot make enough blood cells).
 - **Severe skin reactions**: These include Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN). These are more likely to occur if you are taking other medicines known to cause these skin reactions.For more information on these and other serious side effects, see the **Serious side effects and what to do about them** table, below.
- Leucovorin may lower the effects of anti-epileptic medications such as phenobarbital, primidone and phenytoin. If you are taking anti-epileptic medications, you may be at an increased risk of having seizures more often

What is Leucovorin Calcium Injection USP used for?

Leucovorin Calcium Injection USP is used:

- to lower the toxic effects of:
 - a group of medicines called folic acid antagonists. It is also used to treat an overdose of these medicines
 - methotrexate (a medicine often used to treat cancer)
- to treat some kinds of anemia (low level of red blood cells in the body)
 - due to low level of folate (an essential B vitamin) in the body such as in poor food intake or absorption (sprue, nutritional deficiency); or
 - occurring during pregnancy and infancy.
- before treatment with fluorouracil to improve survival time in the palliative treatment of patients with advanced colorectal cancer.

How does Leucovorin Calcium Injection USP work?

Leucovorin Calcium Injection USP belongs to a class of medicines called folic acid analogs. It:

- lowers the harmful effects of methotrexate by competing with methotrexate and limiting how much methotrexate enters your cells
- treats anemia by supplying folic acid that is needed to produce red blood cell
- increases the effects of 5-fluorouracil (a medicine used to treat cancer)

What are the ingredients in Leucovorin Calcium Injection USP?

Medicinal ingredients: Leucovorin Calcium (also known as calcium folinate).

Non-medicinal ingredients: Hydrochloric acid or sodium hydroxide (to adjust pH).

Leucovorin Calcium Injection USP comes in the following dosage forms:

Solution: 10 mg / mL

Do not receive Leucovorin Calcium Injection USP if:

- you have a type of anemia caused by too little Vitamin B₁₂
- you are allergic (hypersensitive) to calcium folinate or any of the other ingredients of Leucovorin Calcium Injection USP (See What are the ingredients in Leucovorin Calcium Injection USP)?

Leucovorin Calcium Injection USP must NOT be injected into the fluid-filled space between the thin layers of tissue that cover the brain and spinal cord (intrathecally).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you receive Leucovorin Calcium Injection USP. Talk about any health conditions or problems you may have, including if you:

- are currently taking methotrexate and:
 - have aciduria (urine pH less than 7)
 - have or have ever had a build-up of fluid in the chest cavity or the belly area
 - are dehydrated (feeling thirsty, dark yellow urine, dizzy, lightheaded, tired, dry mouth and peeing less than 4 times a day)

- have stomach or bowel issues such as a blockage
- you have trouble with your kidneys
- have diarrhoea
- are pregnant, plan to become pregnant, or are breast-feeding.

Other warnings you should know about:

- **Older people with colorectal cancer.** You could have more side effects. Deaths from severe bowel problems, diarrhea, and dehydration have happened in older people getting leucovorin with fluorouracil.
- **Lab and blood tests:** Your healthcare professional will do blood tests before you receive Leucovorin Calcium Injection USP and/or during treatment to monitor your progress or check for side effects. These tests may check:
 - the level of blood cells in your body.
 - that your liver or kidneys are working properly.
 - the level calcium and other essential minerals—like sodium and potassium (electrolyte) in your blood.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

- If you are receiving leucovorin with fluorouracil (an anticancer medicine):
 - your healthcare professional will monitor you for side effects like diarrhea or painful sores that may make it hard for you to eat, drink, or swallow (stomatitis/mucositis). These are early signs of severe and potentially life-threatening side effects. Talk to your healthcare professional **right away** if you experience any of these side effects. See the **Serious side effects and what to do about them** table, below
 - you may experience increased side effects from fluorouracil
- Leucovorin may lower the effects of anti-epileptic medications such as phenobarbital, primidone and phenytoin. If you are taking anti-epileptic medications you may be at an increased risk of having seizures more often
- Leucovorin must not be mixed in the same infusion as 5-fluorouracil because a precipitate may form

The following may interact with Leucovorin Calcium Injection USP:

- medicines used to treat epilepsy - phenobarbital, primidone, and phenytoin. Your healthcare professional may check blood levels of these medicines and change your dose to prevent increased convulsions (fits).
- a group of medicines called folic acid antagonists). These include:
 - methotrexate (a medicine often used to treat cancer). High doses of leucovorin may lower how well methotrexate works
 - trimethoprim or co-trimoxazole (an antibiotic)
 - pyrimethamine (a medicine used to treat malaria)

- anti-cancer medicines, such as 5-fluorouracil (5FU). Leucovorin may increase the harmful effect of fluorouracil

How you will receive Leucovorin Calcium Injection USP:

- in a healthcare setting under the care of your healthcare professional
- as an injection into the muscle or as an injection or an infusion (drip) into your vein

Usual dose:

Your healthcare professional will work out the right dose of Leucovorin Calcium Injection USP for you.

Overdose:

If you think you, or a person you are caring for, have received too much Leucovorin Calcium Injection USP, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using Leucovorin Calcium Injection USP?

These are not all the possible side effects you may have when taking Leucovorin Calcium Injection USP. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- nausea, vomiting
- red, swollen lips
- dizziness
- fever

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Gastrointestinal toxicity (Severe problems with the digestive system): <ul style="list-style-type: none"> • Diarrhea: persistent or severe • Stomatitis (swelling and redness of the lining of your mouth): painful sores that may make it hard for you to eat, drink, or swallow • Mucositis (ulcers (open sores) and swelling of lining of the bowels and mouth): red, shiny, 			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
or swollen mouth and gums, sores in the mouth or on the gums or tongue, blood in the mouth, pain in the mouth or throat, difficulty swallowing or talking, mild burning, or pain when eating			
COMMON			
Palmar-plantar erythrodysesthesia (Hand and Foot syndrome): red or swollen palms, thick calluses and blisters of the hands and soles of the feet, tingling or burning, tightness of the skin		✓	
UNKNOWN			
Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) (severe skin reactions): redness, blistering and/or peeling of the skin and/or inside the lips, mouth, eyes, nasal passages or genitals, accompanied by fever, chills, tiredness, headache and cough, body aches or swollen glands, raised red or purple skin patches, possibly with blister or crust in the center, swollen lips, mild itching or burning			✓
Allergic reactions: difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat, low blood pressure, confusion, reduced alertness, cold, moist skin, fast breathing, fast heartbeat			✓
Seizures (fit): uncontrollable shaking with or without loss of consciousness			✓
Bone marrow suppression (severe drop in blood cells): bleeding,			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
bruising, chills, fatigue, fever, infections, weakness, shortness of breath or other signs of infection			
Syncope (fainting): a temporary loss of consciousness due to a sudden drop in blood pressure		✓	
Hyperammonemia (high ammonia levels in the blood): confusion, irritability, refusal to eat meat or high protein products		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Leucovorin Calcium Injection USP will be stored by your healthcare professional. It should be kept:

- refrigerated (2°C to 8°C)
- protected from light and freezing
- out of reach and sight of children.

If you want more information about Leucovorin Calcium Injection USP:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug->

[product-database.html](#); the manufacturer's website www.Pfizer.ca, or by calling 1-800-463-6001.

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