

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **LEDERLE LEUCOVORIN®**

#### calcium folinate tablets

Read this carefully before you start taking **LEDERLE LEUCOVORIN** and each time you get a refill. 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 **LEDERLE LEUCOVORIN**.

#### Serious Warnings and Precautions

- LEDERLE LEUCOVORIN should only be used with 5-fluorouracil or methotrexate under the direct supervision of a healthcare professional experienced in the use of anti-cancer medicines.
- LEDERLE LEUCOVORIN can cause serious side effects. In some cases these side effects have been fatal:
  - **Severe skin reactions:** These include Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) and are more likely to occur if you are taking other medicines that are also known to cause these reactions.
  - **Gastrointestinal toxicity:** Inflammation and ulceration of the mucous membranes lining the digestive tract.
  - **Bone marrow suppression:** Large decrease in the production of blood cells and platelets by the bone marrow.
  - **Serious allergic reactions**

For more information on these and other serious side effects, see the **Serious side effects and what to do about them** table, below.

#### What is LEDERLE LEUCOVORIN used for?

LEDERLE LEUCOVORIN is used to:

- reduce the toxic effect of the medicine methotrexate if your body does not process methotrexate well.
- treat certain anemias (when your body does not have enough functional red blood cells) due to folate deficiency, such as in sprue, nutritional deficiency, and certain types of anemia that can happen during pregnancy and infancy.

#### How does LEDERLE LEUCOVORIN work?

LEDERLE LEUCOVORIN is a form of the vitamin folic acid. It reduces the toxic effects of methotrexate by competing with methotrexate to get into normal cells. This means LEDERLE LEUCOVORIN enters normal cells and not methotrexate which keeps them healthy.

#### What are the ingredients in LEDERLE LEUCOVORIN?

Medicinal ingredients: calcium folinate

Non-medicinal ingredients: lactose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate and starch pregelatinized 1500

**LEDERLE LEUCOVORIN comes in the following dosage forms:**

Tablet: 5 mg

**Do not use LEDERLE LEUCOVORIN if:**

- you are allergic (hypersensitive) to calcium folinate or any of the other ingredients of LEDERLE LEUCOVORIN (See **What are the ingredients in LEDERLE LEUCOVORIN?**)
- you have megaloblastic anaemia (a type of anemia where the bone marrow makes large, abnormal red blood cells) due to Vitamin B<sub>12</sub> deficiency

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LEDERLE LEUCOVORIN. Talk about any health conditions or problems you may have, including if you:**

- have symptoms of stomach or intestinal disorders
- are taking any of the following:
  - anti-cancer medicines, such as hydroxycarbamide cytarabine, mercaptopurine, thioguanine
  - medicines to treat epilepsy, such as phenobarbital, primidone, phenytoin and succinimides
  - any medicine known to cause serious skin reactions like Stevens-Johnson Syndrome (SJS) or Toxic Epidermal Necrolysis (TEN)
- are pregnant or breastfeeding
- are lactose intolerant or have one of the following rare hereditary diseases:
  - Galactose intolerance
  - Lapp lactase deficiency
  - Glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in **LEDERLE LEUCOVORIN**.

**Other warnings you should know about**

**Blood tests and monitoring:** LEDERLE LEUCOVORIN can cause abnormal blood test results. Your healthcare professional will do blood tests regularly while you are being treated with LEDERLE LEUCOVORIN. They will check the health of your red and white blood cells and platelets as well as the health of your kidneys and liver. They will decide when to perform blood tests and will interpret the results.

**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 taking LEDERLE LEUCOVORIN together with the anti-cancer medicine 5-fluorouracil (5FU) and you experience mouth inflammation, sores or ulcers, stomach or intestinal pain or diarrhea talk to your healthcare professional immediately. These could be signs of a serious, potentially life-threatening, interaction call **gastrointestinal toxicity**. See the **Serious side effects and what to do about them** table, below.

**The following may interact with LEDERLE LEUCOVORIN:**

- anti-cancer medicines, such as 5-fluorouracil (5FU), methotrexate
- folic acid antagonists, such as cotrimoxazole (used to treat bacterial infections), pyrimethamine (used to treat parasitic infections), and other antibiotics that have an effect on folic acid
- medicines used to treat epilepsy, such as phenobarbital, primidone, phenytoin, succinimides

**How to take LEDERLE LEUCOVORIN:**

- Take LEDERLE LEUCOVORIN exactly as your healthcare professional tells you to.

**Usual dose:**

Your healthcare professional will decide on the dose that is right for you based on your weight, other medicines you are taking and the condition that is being treated.

**Overdose:**

If you think you, or a person you are caring for, have taken too much LEDERLE LEUCOVORIN, 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 LEDERLE LEUCOVORIN?**

These are not all the possible side effects you may have when taking LEDERLE LEUCOVORIN. 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	
<b>VERY COMMON</b>			
<b>Gastrointestinal toxicity (inflammation and ulceration of the mucous membranes lining the digestive tract):</b> painful, red, shiny or swollen gums, tongue, mouth or throat sores or ulcers, blood in the mouth, difficult or painful swallowing or talking, dry mouth, mild burning, or pain when eating food, diarrhea			✓
<b>COMMON</b>			

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	
<b>Palmar-plantar erythrodysesthesia (hand and foot syndrome):</b> red or swollen palms, thick calluses and blisters of the hands and soles of the feet, tingling or burning, tightness of the skin		✓	
<b>RARE</b>			
<b>Seizures (fit):</b> uncontrollable shaking with or without loss of consciousness			✓
<b>Syncope (fainting):</b> a temporary loss of consciousness due to a sudden drop in blood pressure		✓	
<b>UNKNOWN FREQUENCY</b>			
<b>Allergic reactions:</b> 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			✓
<b>Bone marrow suppression (large decrease in the production of blood cells and platelets by the bone marrow):</b> bleeding, bruising, chills, fatigue, fever, infections, weakness, shortness of breath or other signs of infection			✓
<b>Hyperammonemia (high ammonia levels in the blood):</b> confusion, irritability, refusal to eat meat or high protein products		✓	
<b>Severe skin reactions [Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)]:</b> 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			✓

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	
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			

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:

Store at 15°C - 30°C. Protect from light.

Keep out of reach and sight of children.

### If you want more information about LEDERLE LEUCOVORIN:

- 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](http://www.Pfizer.ca), or by calling 1-800-463-6001.

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