

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

ONCASPAR®* (õn-kă-spăř) Pegaspargase Injection

Read this carefully before you start taking **ONCASPAR** 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 **ONCASPAR**.

What is ONCASPAR used for?

ONCASPAR is used to treat acute lymphoblastic leukaemia (ALL). ALL is a white blood cell cancer type in which certain immature white cells (named lymphoblasts) start growing out of control thus preventing the production of functional blood cells. ONCASPAR is used together with other medicines.

How does ONCASPAR work?

ONCASPAR contains pegaspargase, which is an enzyme that breaks down L-asparagine, an important building block of proteins without which cells cannot survive. Normal cells can make L-asparaginase for themselves, while some cancer cells cannot. ONCASPAR lowers L-asparagine level in blood cancer cells and stops the cancer cells growing.

What are the ingredients in ONCASPAR?

Medicinal ingredient:

- Pegaspargase

Non-medicinal ingredients:

- Dibasic Sodium Phosphate
- Monobasic Sodium Phosphate
- Sodium Chloride
- Water for injection

ONCASPAR comes in the following dosage form:

Solution for Injection/Infusion

Do not use ONCASPAR if you:

- are allergic to pegaspargase or to any of the other ingredients of this medicine.
- have severe reduced liver function.
- ever had blood clots with prior L-asparaginase therapy.
- ever had pancreatitis.
- ever had severe bleeding with prior L-asparaginase therapy.

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

- have had serious allergic reactions to other forms of L-asparaginase, for example, itching, flushing or swelling of the airways, because major allergic reactions to ONCASPAR can occur.
- suffer from a bleeding disorder or had serious blood clots.
- get a fever. This medicine may make you more susceptible to infections.
- have had poor liver function or are taking other medicines which may harm the liver. When ONCASPAR is used in combination with other cancer treatments, liver and central nervous system damage can occur.
- suffer abdominal pain that may radiate to the back. Inflammation of the pancreas, that in some cases caused death, can occur with ONCASPAR treatment.

Other warnings you should know about:

Higher than normal blood and urine sugar levels can occur in patients with ONCASPAR.

This medicine can lead to fluctuation in clotting factors and may increase the risk of bleeding and/or clotting.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your healthcare professional for advice before taking this medicine.

You should not take ONCASPAR if you are pregnant because its effects during pregnancy have not been studied. Your healthcare professional will decide whether your disease requires treatment. You must use reliable contraception during treatment, and for at least 6 months after ONCASPAR treatment was discontinued. Ask your healthcare professional for advice on the best contraceptive method that you can use.

It is not known whether pegaspargase is excreted into the breast milk. The decision to stop breast-feeding or stop ONCASPAR treatment should be discussed with your healthcare professional.

Do not drive or use machines when taking this medicine because it may make you feel drowsy, tired or confused.

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

The following may interact with ONCASPAR:

- immunisation with live vaccines within three months of completing your leukaemia treatment. This will increase the risk of severe infections.
- vincristine, another cancer medicine. If taken at the same time as ONCASPAR there is an increased risk of side effects or allergic reactions.
- medicines which reduce the blood's ability to clot such as anticoagulants (e.g. warfarin and heparin), dipyridamol, acetylsalicylic acid or nonsteroidal anti-inflammatory drugs. If taken at the same time as ONCASPAR there is a higher risk of bleeding disorders.
- medicines which require cell division for their effect (e.g. methotrexate, a medicine used for cancer as well as arthritis).
- prednisone, a steroid medicine. If taken at the same time as ONCASPAR the effects on the clotting ability of your blood are increased.
- cytarabine, a medicine which can be used in cancer treatment and, could interfere with the effects of ONCASPAR.

ONCASPAR can also cause changes in liver function which can affect the way other medicines work.

How to take ONCASPAR:

ONCASPAR is given by intramuscular injection or intravenous infusion. This product should be administered by your healthcare professional only.

Usual dose:

Your healthcare professional will determine the dose of ONCASPAR you will receive. The dose you receive will be based on your age, and body surface area or body weight.

Overdose:

If you think you have been administered too much ONCASPAR, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss your scheduled treatment, contact your healthcare professional as soon as possible to schedule your next treatment.

What are possible side effects from using ONCASPAR?

The following side effects were observed with different frequencies in patients receiving ONCASPAR: very common side effects (i.e., more than one patient out of every 10 patients) included serious allergic reactions with the following events (rash, itching, red swellings of the skin, hives, and difficult breathing, fast heartbeat, and drop in blood pressure), abdominal pain, diarrhea, rash and generalized weakness.

The following commonly (more than 1 patient out of every 100 patients) observed side effects were: vomiting, pain in the limbs and joints, infections that can be severe with high fever and confusion or loss of consciousness. Also inflammation of the pancreas which can result in pain in the upper abdomen, nausea, vomiting and high blood sugar. Inflammation of the mouth and lips or damage to nerves (may decrease sensation, balance, and cause muscle weakness or loss of consciousness or uncontrolled shaking of the body (convulsions) were also observed. Other events included low grade fever associated with low white blood cells, decrease in the amount of red blood cells (feeling tired, weakness, with difficult breathing, formation of a blood clot, bruising or severe bleeding. Rare side effects (not more than 1 out of every 1000 patients) include reversible posterior leukoencephalopathy syndrome (RPLS), a syndrome characterized by headache, confusion, high blood pressure, seizures and visual loss which resolves after some time. Very rare side effects (not more than 1 out of every 10,000 patients) include mild twitching of the fingers and fluid in the abdominal area (increase in size of abdominal area).

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			
Serious allergic reactions: rash, itching, swelling, hives, shortness of breath, fast heartbeat, and drop in blood pressure		√	√
Abdominal pain	√		

Blood bilirubin increase		√	
Diarrhea	√		
High blood sugar levels		√	
Inflammation of the pancreas: pain the upper abdomen, nausea, vomiting (pancreatitis)			√
Rash	√		
Generalized weakness	√		
Formation of a blood clot		√	
Severe infection with very high fever		√	
COMMON			
Vomiting	√		
Pain in the limbs and joints		√	
Damage to nerves: may impair sensation, balance, movement, gland or organ function, and cause muscle weakness or loss of consciousness		√	
Inflammation of the mouth and lips		√	
Fever with low white blood cells		√	
Decrease in the amount of red blood cells: feeling tired, weakness, shortness of breath with oxygen supply to the body or a region of the body		√	
Infections and sepsis: high fever , increased heart rate, increased breathing rate, confusion		√	
Bruising or severe bleeding		√	
High blood levels of lipid(s)	√		
Convulsion: uncontrolled shaking of body		√	
Investigations: amylase increased, alanine aminotransferase increase, neutrophil count decreased, platelet count decreased, activated partial thromboplastin time prolonged		√	
Build-up of fluid in the stomach (ascites)		√	
RARE			
Loss of kidney function (reversible)		√	
Visual disturbance		√	

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

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect;
- By calling 1-866-234-2345 (toll-free);
- By completing a Patient Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Patient Side Effect Reporting Form are available at MedEffect.

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:

Keep refrigerated prior to use at 2°C to 8°C. Do not freeze or shake. Store vials in the original package to protect from light.

This product is to be stored and administered by a healthcare professional only.

Keep out of reach and sight of children.

If you want more information about ONCASPAR:

- 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; the manufacturer's website www.servier.ca, or by calling 1-800-363-6093.

This leaflet was prepared by :

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