PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

ASPARLAS®

Calaspargase pegol for injection

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

What is ASPARLAS used for?

ASPARLAS is used to treat acute lymphoblastic leukaemia (ALL) if you are aged 1 to 21 years. 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. ASPARLAS is used together with other medicines.

How does ASPARLAS work?

ASPARLAS contains calaspargase pegol, 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-asparagine for themselves, while some cancer cells cannot. ASPARLAS lowers L-asparagine level in blood and stops the cancer cells growing.

What are the ingredients in ASPARLAS?

Medicinal ingredients: calaspargase pegol

Non-medicinal ingredients: Monobasic Sodium Phosphate, Dibasic Sodium Phosphate Heptahydrate, Sodium Chloride, Water for Injection.

ASPARLAS comes in the following dosage forms:

Solution for Infusion.

Do not use ASPARLAS if you:

- are allergic to calaspargase pegol 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 take ASPARLAS. Talk about any health conditions or problems you may have, including if you:

- have had serious allergic reactions to other forms of L-asparaginase (e.g. pegaspargase), for example, itching, flushing or swelling of the airways, because major allergic reactions to ASPARLAS can occur.
- suffer from a bleeding disorder or had serious blood clots.
- have 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 ASPARLAS is used in combination with other cancer treatments, liver and central nervous system damage can occur.
- have pre-existing liver disease, you may be at higher risk of developing hepatotoxicity following treatment with Asparlas. If you experience symptoms of rapid weight gain, fluid retention with ascites (abdominal swelling), and hepatomegaly (liver enlargement), talk to your doctor immediately.
- suffer abdominal pain that may radiate to the back. Inflammation of the pancreas, that in some cases caused death, can occur with ASPARLAS treatment.

Other warnings you should know about:

- This medicine can lead to fluctuation in clotting factors and may increase the risk of bleeding and/or clotting.
- There is a risk of higher than normal blood and urine sugar levels (known as hyperglycemia and glucose intolerance). You should seek medical advice if you experience excessive thirst or any increase in the volume or frequency of urination.
- Higher than normal blood and urine sugar levels, and lipids levels, can occur in patients with ASPARLAS.
- 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.
- If you are a female patient that can become pregnant during the treatment, you must use a reliable non-oral, contraception during treatment, and for at least 3 months after ASPARLAS treatment was discontinued. Ask your healthcare professional for advice on the best contraceptive method that you can use.
- You should not take ASPARLAS if you are pregnant because its effects during pregnancy have not been studied. Your healthcare professional will decide whether your disease requires treatment.
- It is not known whether calaspargase pegol is excreted into the breast milk. The decision to stop breast-feeding or stop ASPARLAS 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 ASPARLAS:

No drug interaction studies have been conducted with ASPARLAS. However, the following may interact with ASPARLAS:

- 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 ASPARLAS 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 ASPARLAS 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 ASPARLAS 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 ASPARLAS.

ASPARLAS can also cause changes in liver function which can affect the way other medicines work, including oral contraceptives.

How to take ASPARLAS:

- ASPARLAS is given by intravenous infusion. This product should be administered by your healthcare professional only.

Usual dose:

Your healthcare professional will determine the dose of ASPARLAS 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, or a person you are caring for, have taken too much ASPARLAS, contact a 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 ASPARLAS?

These are not all the possible side effects you may have when taking ASPARLAS.

The following side effects were observed in patients receiving ASPARLAS in combination with other chemotherapy drugs:

- Nausea, vomiting, diarrhea, abdominal pain, decreased appetite, dehydration, weight decreased, mouth sores, cough
- High blood pressure, low blood pressure, fever, fainting, low oxygen levels that may cause shortness of breath, skin infection
- Depression, headache, back pain, pain in extremity, nerve damage affecting movement, numbness or tingling in arms or legs
- Side effects related to certain laboratory abnormalities may occur, such as tiredness or paleness due to low number of red blood cells, rapid breathing or confusion due to high acid levels in the blood, high levels of potassium leading to weakness or irregular heartbeat, low levels of sodium in the blood leading to tiredness or confusion

If you experience any side effects not listed here, tell your healthcare professional.

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			
Inflammation of the pancreas (pancreatitis): pain in the upper abdomen that may radiate to your back, nausea, vomiting, fever, low blood pressure		✓	✓
Increased/excess sugar in the blood (symptoms: excessive thirst, increased urinary frequency)		✓	
Common			
Severe allergic reaction that may cause loss of consciousness and could be life-threatening (including anaphylactic reaction): hives, itching, flushed or pale skin, tightening of the throat, tingling sensation of the lips or throat, swollen tongue or throat, wheezing, shortness of breath, dizziness or fainting, low blood pressure etc.		✓	✓
Formation of a blood clot (thrombosis, embolism): severe headache, arm or leg swelling, shortness of breath, chest pain or stroke.		✓	✓
Serious infection (including viral, fungal or bacterial infections, sepsis, bacterial sepsis, infection of the lung, infection of the intestine): high fever, chills, low blood pressure, rash, body ache, chest pain, cough, shortness of breath, diarrhea, bloody stool etc.		✓	
Having severe diarrhea (10 or more loose, watery stools) in a day, or blood in stools, with or without abdominal pain (severe diarrhea, colitis, enterocolitis, neutropenic colitis)		✓	
Neurological disorders (seizure, encephalopathy, etc.): symptoms may include a headache, confusion, high blood pressure, fits and visual loss which resolves after some time.		✓	
Uncommon			
Liver inflammation (hepatitis, hepatotoxicity, or hepatic infection fungal): jaundice, frequent nausea or vomiting, or easy bruising or bleeding		✓	
Abnormal bleeding: unusual bleeding or bruising of the skin or gum, bloody stool, stroke, coughing blood, etc.		✓	
Not Known			
A serious type of liver damage (veno-occlusive disease [VOD] or sinusoidal obstruction syndrome [SOS]): symptoms may include rapid weight gain, fluid retention in the abdomen ((ascites) causing abdominal swelling and enlarged liver (hepatomegaly)		✓	✓

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/adverse-reaction-reporting.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:

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. Unopened vials may be stored at room temperature (15°C to 25°C) for no more than 48 hours.

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 ASPARLAS:

- 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.servier.ca, or by calling 1-800-363-6093.

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