

ONCASPAR®

Pegaspargase powder for solution for injection/infusion

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ONCASPAR.

It does not contain all of the available information. All medicines have risks and benefits. Your doctor has weighed the risks of using your medicine against the benefit that it will have for you.

It does not take the place of talking to your doctor or pharmacist.

If you have any concerns about having this medicine, ask your doctor or pharmacist.

Please read this leaflet carefully and keep it for future reference.

Please also note that this leaflet is subject to change, therefore, ask your doctor whether this is the latest information regarding this medicine.

What is ONCASPAR

ONCASPAR contains pegaspargase which is a form of an enzyme called asparaginase. This enzyme breaks down to asparagine, an important building block in making proteins, without which cells cannot survive. ONCASPAR lowers asparagine levels in blood cancer cells and stops the cancer growing.

Pegaspargase may sometimes be called pegylated (or "PEG") asparaginase.

What ONCASPAR is used for

ONCASPAR is used to treat leukaemia. It belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is no evidence that it is addictive.

This medicine is available only with a doctor's prescription.

Before being treated with ONCASPAR

ONCASPAR must not be given if you:

- are allergic to pegaspargase or any of the ingredients listed at the end of this leaflet
- if you have ever had blood clots following asparaginase therapy
- if you have ever had pancreatitis (inflammation of the pancreas)
- if you have ever had severe bleeding following asparaginase therapy

Tell your doctor if you are pregnant or plan to become pregnant.

Like most cytotoxic medicines ONCASPAR is not recommended for use during pregnancy. If there is any need to consider this medicine during

your pregnancy, your doctor will discuss with you the benefits and risks of using it.

Do not breastfeed if you are taking this medicine.

The active ingredient in ONCASPAR may pass into breast milk and there is a possibility that your baby may be affected.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before treatment with ONCASPAR

You should be treated with ONCASPAR by a doctor who is trained in treating patients with leukaemia. Treatment will normally take place in a hospital because of the need for hospital facilities and skilled personnel.

You should tell your doctor:

- if you have had serious allergic reactions to other forms of asparaginase, for example itching, flushing or swelling of the airways, because major allergic reactions to ONCASPAR can occur.
- if you suffer from a bleeding disorder or had serious blood clots.
- if you get a fever. This medicine may make you more susceptible to infections.
- if you 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.

- if you have or have had liver, lung or heart disease.
- if you suffer abdominal pain. Inflammation of the pancreas can occur with ONCASPAR that in some cases can cause death if left untreated.

If you have not told your doctor about any of the above, tell your doctor before you are given ONCASPAR.

If you are the parent of a child being treated with ONCASPAR, tell the doctor if any of the above conditions apply to your child.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines and ONCASPAR may interfere with each other. In particular, tell your doctor if you are using:

- immunisation with live vaccines within 3 months of completing your leukaemia treatment. This will increase the risk of severe infections
- other medicines used to treat leukaemia or cancer
- medicines which reduce blood clotting such as anticoagulants (e.g. warfarin and heparin), aspirin and other anti-inflammatory medicines

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

Ask your doctor or other healthcare professional if you are not sure about this list of medicines.

You may need to take different amounts of your medicines or you may need to use different medicines.

Your doctor or pharmacist will have more information to be careful with or avoid while taking this medicine.

How ONCASPAR is given

How much is given

ONCASPAR must only be given by healthcare professionals trained in administering anticancer medicines.

Your doctor will decide upon the doses you will receive and how often. This depends on your, age, body weight and height.

ONCASPAR may be given in combination with other drugs.

How ONCASPAR is given

ONCASPAR is given by injection into a muscle (intramuscular) or, if not suitable, into a vein (intravenous).

Ask your doctor if you want more information about the dose of ONCASPAR and the other medicines you will be receiving and how they are given while you are being treated with ONCASPAR.

Overdose

As ONCASPAR is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you experience severe side effects after being given this medicine, tell your doctor or nurse immediately.

You may need urgent medical attention.

While being treated with ONCASPAR

Things you must do

Keep all appointments with your doctor and always discuss with your doctor any problems during or after treatment with ONCASPAR.

Do not start taking any other medicines, prescription or over-the-counter, without first telling your doctor.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given ONCASPAR.

ONCASPAR, like all other medicines, may cause unwanted side effects. Side effects are very common with anti-cancer medicines such as ONCASPAR and they may be serious. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Tell your doctor immediately if you get any of the following side effects:

- Serious allergic reactions with symptoms such as rash, itching, swelling, hives, shortness of breath, fast heart beat and drop in blood pressure
- Severe bleeding or bruising
- Inflammation or other disorders of the pancreas causing severe stomach pain which may spread to your back (pancreatitis)
- Violent shaking (seizures) and loss of consciousness
- Headaches, high blood pressure and visual disturbances, which are symptoms of a condition called encephalopathy

- Loss of kidney function (e.g. change in urine output, swelling of feet and ankles)
- Very high fever
- Problems with your liver (elevated enzymes)
- Fast heart rate, breathing difficulty, and weakness;
- Increase in blood sugar levels (hyperglycaemia).

The above side effects may be serious. You may need urgent medical attention.

Tell your doctor as soon as possible if you experience any side effects, including any side effects not listed below.

Very common side effects (may affect more than 1 in 10 people)

- Loss of appetite, feeling sick, being sick, stomach cramps, diarrhoea or weight loss
- Pain or swelling at the injection site

Common side effects (may affect up to 1 in 10 people)

- Agitation, confusion and drowsiness
- Changes in EEG (a trace of the electrical activity of your brain)
- Changes in the function of the pancreas
- Fever and flu-like symptoms
- Mouth sores
- Back, joint or abdominal pain

Uncommon side effects (may affect up to 1 in 100 people)

- Swollen salivary glands (parotitis)
- Increased levels of uric acid and ammonia in the blood

Rare/very rare side effects (affect less than 1 in 1,000 people)

- Encephalopathy, characterised by headache, confusion, seizures and visual loss which resolves after some time
- Mild twitching of the fingers

- Reduced thyroid function which may cause tiredness, weight gain and feeling cold

Your doctor has information on monitoring for such side effects and their treatment.

ONCASPAR may also cause the following side effects:

- Anaemia, bleeding disorder (coagulopathy), decreased count of white cells in your blood, decreased count of platelets in your blood.
- Damage to or disease affecting nerves (peripheral neuropathy), which may impair sensation, movement, gland or organ function.
- Dehydration
- Blood cholesterol increase.
- Increased level of calcium in your blood (hypercalcaemia).
- Abnormally low level of sodium in your blood (hyponatremia).

- Sodium dihydrogen phosphate monohydrate
- Disodium phosphate heptahydrate
- Sodium chloride
- Sucrose
- Sodium hydroxide (for pH adjustment)
- Hydrochloric acid (for pH adjustment)

Name and address of the sponsor

ONCASPAR is distributed in Australia by:

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www.servier.com.au

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Australia

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Storage

It is unlikely that you will be asked to store ONCASPAR yourself. It will usually be stored in the pharmacy or on the ward.

Product Description

What ONCASPAR looks like?

ONCASPAR is a white to off white powder. After reconstitution, the solution is clear, colourless and free from visible foreign particles.

Each pack contains 1 glass vial with 3,750 U pegaspargase.

Active ingredient:

Pegaspargase.

Each vial contains 750 units per 1 mL (3,750 units in 5 mL)

ONCASPAR also contains: