

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 asparagine, an important building block in making proteins, without which cells cannot survive. Normal cells can make asparagine for themselves, while some cancer cells cannot. 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
- have severe hepatic (liver) disease.
- have ever had pancreatitis (inflammation of the pancreas)
- have ever had blood clots following asparaginase therapy
- have ever had severe bleeding following asparaginase therapy.

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.

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. Men must also use effective contraception while they or their partners are being treated with ONCASPAR.

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 have 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.

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

A side effect called osteonecrosis (bone damage) has been reported in children and adolescents receiving ONCASPAR (higher incidence seen in girls), when taken at the same time as glucocorticoids (e.g. dexamethasone). Glucocorticoids are medicines used to treat many different conditions including severe allergies, asthma, skin problems, and inflammatory diseases.

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, it is especially important to tell your doctor if you are using any of the following medicines:

- 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), dipyridamol, aspirin and other anti-inflammatory medicines. If used at the same time as ONCASPAR, there is a higher risk of bleeding disorders
- medicines which require cell division for their effect, for example, methotrexate (a medicine used for cancer as well as arthritis treatment) may have a decrease in its effect.
- prednisone, a steroid medicine. If used at the same time as ONCASPAR, the effects on the clotting ability of your blood are increased.
- Glucocorticoids when used at the same time as ONCASPAR may increase the risk of steroid-induced osteonecrosis (bone damage) in children and adolescents, with a higher incidence seen in girls. Therefore, if you experience any new bone pain (i.e. pain in hip, knee or back), inform your doctor as soon as possible.

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). Before administration, you might receive a combination of medicines which may include paracetamol, and an antihistamine to help reduce your chances of getting allergic reactions. Your doctor will decide whether such premedication is necessary.

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.

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

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 or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects:

- Serious allergic reactions that may cause loss of consciousness and could be life-threatening (anaphylactic shock) with symptoms such as rash, itching, swelling, hives, shortness of breath, fast heartbeat and drop in blood pressure
- Severe skin reaction called toxic epidermal necrolysis
- Violent shaking (seizures) and loss of consciousness
- Very high fever.

Tell your doctor immediately if you notice any of these serious side effects:

- Inflammation or other disorders of the pancreas (pancreatitis) causing severe stomach pain which may spread to your back, vomiting, increase in blood sugar levels (hyperglycaemia)
- 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)
- Problems with your liver (e.g., change in colour of your skin or urine or stool)
- Fast heart rate, breathing difficulty, and weakness
- Leg pain (which could be a symptom of thrombosis), chest pain or shortness of

breath (which may be a symptom of blood clots in the lungs, called pulmonary embolism).

- Bone damage (osteonecrosis)

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, general weakness or weight loss
- Pain or swelling at the injection site
- Blood clots
- Fever with low counts of white blood cells.

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

- Changes in EEG (a trace of the electrical activity of your brain)
- Severe bleeding or bruising
- Severe infection with very high fever
- Laboratory results of elevated liver enzymes or bilirubin)
- Decreased number of red blood cells
- Build-up of fluid in the stomach (ascites)
- Fever and flu-like symptoms
- Mouth sores
- Back, joint or abdominal pain
- High levels of fat and cholesterol in your blood; low potassium in your blood.

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

- Swollen salivary glands (parotitis).

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

- Liver failure, jaundice, blocked bile flow from the liver (cholestasis), destruction of liver cells (liver cell necrosis)
- 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.

Not known (frequency cannot be estimated from the available data)

- Stroke
- Fever
- Decreased number of white blood cells and platelets
- Palpitations
- Cysts in your pancreas, swelling of the salivary glands
- High levels of urea in your blood; antibodies against ONCASPAR high levels of ammonia in your blood; decreased blood sugar levels
- Bone damage (osteonecrosis)
- Sleepiness, confusion.

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

ONCASPAR may also cause the following side effects:

- Anaemia
- Damage to, or disease affecting nerves (peripheral neuropathy), which may

impair sensation, movement, gland or organ function

- Dehydration
- Increased level of calcium in your blood (hypercalcaemia)
- Abnormally low level of sodium in your blood (hyponatremia).

Storage

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

- 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:

Servier Laboratories (Aust.) Pty Ltd
www.servier.com.au
8 Cato Street
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Hawthorn 3122 Victoria
Australia

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