

ONCASPAR®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ONCASPAR?

ONCASPAR contains pegaspargase which is a form of an enzyme called asparaginase. Pegaspargase may sometimes be called pegylated (or "PEG") asparaginase. 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.

For more information, see Section [1. Why am I using ONCASPAR?](#) in the full CMI.

2. What should I know before I use ONCASPAR?

Do not use if you have ever had an allergic reaction to ONCASPAR or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ONCASPAR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ONCASPAR and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ONCASPAR?

ONCASPAR must only be given by healthcare professionals trained in administering anticancer medicines. ONCASPAR is given by injection into a muscle (intramuscular) or, if not suitable, into a vein (intravenous). 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. Your doctor will decide whether premedication is necessary.

More instructions can be found in Section [4. How do I use ONCASPAR?](#) in the full CMI.

5. What should I know while using ONCASPAR?

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|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">● Remind any doctor, nurse, dentist or pharmacist you visit that you are using ONCASPAR.● Keep all appointments with your doctor and always discuss with your doctor any problems during or after treatment with ONCASPAR. |
| Things you should not do | <ul style="list-style-type: none">● Do not start taking any other medicines, prescription or over-the-counter, without first telling your doctor. |
| Driving or using machines | <ul style="list-style-type: none">● Do not drive or use machines when using ONCASPAR because it may make you feel drowsy, tired or confused. |
| Looking after your medicine | <ul style="list-style-type: none">● It is unlikely that you will be asked to store ONCASPAR yourself. It will usually be stored in |

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| | the pharmacy or on the hospital/clinic ward. |
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For more information, see Section [5. What should I know while using ONCASPAR?](#) in the full CMI.

6. Are there any 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. If you experience serious allergic reactions 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, severe stomach pain which may spread to your back, vomiting, increase in blood sugar levels, headaches, high blood pressure, visual disturbances, change in urine output, swelling of the feet and ankles, change in colour of your skin or urine or stool, fast heart rate, breathing difficulty and weakness, leg pain, chest pain or shortness of breath after taking ONCASPAR – please seek urgent medical attention.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ONCASPAR®

Active ingredient(s): *Pegaspargase powder for solution for injection/infusion*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ONCASPAR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ONCASPAR.**

Where to find information in this leaflet:

- [1. Why am I using ONCASPAR?](#)
- [2. What should I know before I use ONCASPAR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ONCASPAR?](#)
- [5. What should I know while using ONCASPAR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using 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.

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.

2. What should I know before I use ONCASPAR?

Warnings

Do not use ONCASPAR if:

- you are allergic to pegaspargase or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- 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.

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.
- if ONCASPAR is used in combination with other cancer treatments, liver damage (severe, life-threatening, and potentially fatal cases of hepatic veno-occlusive disease (VOD)) can occur.
- if ONCASPAR is used in combination therapy this may result in injury to central nervous system.
- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

It is important to tell your doctor if you are pregnant or intend to become pregnant, or if you are breastfeeding or intend to breastfeed.

Pregnancy

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.

Breastfeeding

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ONCASPAR.

4. How do I use 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.

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.

If you use too much ONCASPAR

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.

5. What should I know while using ONCASPAR?

Things you should 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.

Driving or using machines

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

Looking after your medicine

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.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

| Serious side effects | What to do |
|---|--|
| <p data-bbox="204 432 571 477">Gastrointestinal</p> <ul data-bbox="204 510 770 920" style="list-style-type: none"><li data-bbox="204 510 770 846">● Inflammation or other disorders of the pancreas (pancreatitis) causing severe stomach pain which may spread to your back<li data-bbox="204 869 435 920">● Vomiting <p data-bbox="204 965 746 1010">Kidney and liver related</p> <ul data-bbox="204 1048 770 1503" style="list-style-type: none"><li data-bbox="204 1048 770 1272">● Loss of kidney function (e.g. change in urine output, swelling of feet and ankles)<li data-bbox="204 1294 770 1503">● Problems with your liver (e.g. change in colour of your skin or urine or stool) <p data-bbox="204 1559 703 1603">Respiratory and heart</p> <ul data-bbox="204 1641 770 1921" style="list-style-type: none"><li data-bbox="204 1641 770 1921">● Chest pain or shortness of breath (which may be a symptom of blood clots in the lungs, called pulmonary embolism) | <p data-bbox="810 432 1377 819">Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

| Serious side effects | What to do |
|--|-------------------|
| <ul style="list-style-type: none"> ● Fast heartbeat, fast heart rate, breathing difficulty, and weakness <p>Blood and investigations</p> <ul style="list-style-type: none"> ● Increase in blood sugar levels (hyperglycaemia) ● Drop in blood pressure ● Decreased number of white blood cells <p>Musculoskeletal</p> <ul style="list-style-type: none"> ● Bone damage (osteonecrosis) ● Leg pain (which could be a symptom of thrombosis) <p>Nervous system</p> <ul style="list-style-type: none"> ● Headaches, high blood pressure and visual disturbances, which are symptoms of a condition called encephalopathy ● Serious allergic reactions that may cause loss of consciousness and | |

| Serious side effects | What to do |
|--|-------------------|
| <p>could be life-threatening (anaphylactic shock)</p> <ul style="list-style-type: none"> • Violent shaking (seizures) and loss of consciousness <p>Skin</p> <ul style="list-style-type: none"> • Rash, itching, swelling, hives • Severe skin reaction called toxic epidermal necrolysis <p>General</p> <ul style="list-style-type: none"> • Very high fever | |

Less serious side effects

| Less serious side effects | What to do |
|---|---|
| <p>Gastrointestinal</p> <ul style="list-style-type: none"> • Loss of appetite, feeling sick, being sick, stomach cramps, diarrhoea, general weakness or weight loss • Build-up of fluid in the stomach (ascites) • Cysts in your pancreas | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

| Less serious side effects | What to do |
|--|-------------------|
| <p>Kidney and liver related</p> <ul style="list-style-type: none"> • Laboratory results of elevated liver enzymes or bilirubin) • Liver failure, jaundice, blocked bile flow from the liver (cholestasis), destruction of liver cells (liver cell necrosis) <p>Respiratory and heart</p> <ul style="list-style-type: none"> • Palpitations <p>Blood and investigations</p> <ul style="list-style-type: none"> • Blood clots • Fever with low counts of white blood cells • Severe bleeding or bruising • Decreased number of red blood cells • Decreased number of platelets • High levels of fat and cholesterol in your blood • Low potassium in your blood | |

| Less serious side effects | What to do |
|---|-------------------|
| <ul style="list-style-type: none"> ● Reduced thyroid function which may cause tiredness, weight gain and feeling cold ● High levels of urea in your blood ● Antibodies against ONCASPAR ● High levels of ammonia in your blood ● Decreased blood sugar levels ● Anaemia ● Increased level of calcium in your blood (hypercalcemia) ● Abnormally low level of sodium in your blood (hyponatremia) <p>Musculoskeletal</p> <ul style="list-style-type: none"> ● Back, joint or abdominal pain ● Bone damage (osteonecrosis) ● Pain or swelling at the injection site <p>Mouth</p> | |

| Less serious side effects | What to do |
|---|-------------------|
| <ul style="list-style-type: none"> ● Mouth sores ● Swollen salivary glands (parotitis) <p>Nervous system</p> <ul style="list-style-type: none"> ● Changes in EEG (a trace of the electrical activity of your brain) ● Mild twitching of the fingers ● Sleepiness, confusion ● Damage to, or disease affecting nerves (peripheral neuropathy), which may impair sensation, movement, gland or organ function ● Encephalopathy, characterised by headache, confusion, seizures and visual loss which resolves after some time ● Stroke <p>General</p> <ul style="list-style-type: none"> ● Severe infection with very high fever | |

| Less serious side effects | What to do |
|--|------------|
| <ul style="list-style-type: none"> • Fever and flu-like symptoms • Dehydration | |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. Your doctor has information on monitoring for such side effects and their treatment.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

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

What ONCASPAR contains

| | |
|---|---|
| Active ingredient (main ingredient) | Pegaspargase powder for solution for injection/ infusion |
| Other ingredients (inactive ingredients) | Sodium dihydrogen phosphate monohydrate Disodium phosphate heptahydrate Sodium chloride Sucrose Sodium hydroxide (for pH adjustment) Hydrochloric acid (for pH adjustment) |

Do not take this medicine if you are allergic to any of these ingredients.

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.

(Aust R 303807).

Who distributes ONCASPAR

Servier Laboratories (Aust.) Pty. Ltd.

www.servier.com.au

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