

## 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.

This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using Enrylaze?

Enrylaze contains the active ingredient recombinant crisantaspase. Enrylaze is used to treat patients with acute lymphoblastic leukaemia (ALL) and lymphoblastic lymphoma (LBL) alongside other medicines. It works by decreasing an amino acid called “asparagine” needed by ALL/LBL cancer cells to survive.

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

### 2. What should I know before I receive Enrylaze?

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

**Do not use if you are currently experiencing or have experienced serious problems with your pancreas (severe pancreatitis).**

**Do not use if you have experienced serious blood clots or serious bleeding events after being treated with asparaginase or Enrylaze. 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 Enrylaze?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may increase the risk of side effects with Enrylaze or interfere with 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 will I be given Enrylaze?

Enrylaze can only be initiated by a doctor with experience in using medicines to treat cancer. Your doctor will determine what dose you are given and whether it will be given to you via infusion into your veins or an injection into your muscle. Your doctor will calculate the dose you need.

More instructions can be found in Section [4. How will I be given Enrylaze?](#) in the full CMI.

### 5. What should I know while using Enrylaze?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Enrylaze. Tell your doctor you are being treated with Enrylaze if you are about to start on a new medicine.</li><li>• Check with your doctor if you are pregnant or intend to become pregnant.</li><li>• Check with your doctor if you are breastfeeding or intend to breastfeed.</li><li>• Call your doctor straight away if you have any of the serious side effects listed in <a href="#">6. Are there any side effects?</a></li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Enrylaze can cause you to feel sick and have a headache. This may impact your ability to drive and operate machinery</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Your doctor or pharmacist has more information on how to store Enrylaze.</li></ul>

For more information, see Section [5. What should I know while using Enrylaze?](#) in the full CMI.

### 6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The most common side effects include blood cell abnormalities including low red cell and white cell counts, vomiting, nausea, fatigue, fever, decreased appetite, liver function test abnormalities, abdominal pain, headache and diarrhoea

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.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# Enrylaze<sup>®</sup>

Active ingredient(s): *Recombinant crisantaspase*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Enrylaze. **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 Enrylaze.**

Where to find information in this leaflet:

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

## 1. Why am I using Enrylaze?

Enrylaze contains the active ingredient recombinant crisantaspase, which is an enzyme produced by recombinant DNA technology.

Enrylaze is used to treat acute lymphoblastic leukaemia (ALL) and lymphoblastic lymphoma (LBL) in combination with other medicines in adults and children who have developed an allergic reaction (hypersensitivity) to *E. coli*-derived asparaginase.

**This enzyme works by decreasing the levels of an amino acid called 'asparagine' which is needed by ALL and LBL cancer cells to survive.** Leukaemic cells are unable to make their own asparagine and die when asparagine is removed by Enrylaze.

## 2. What should I know before I use Enrylaze?

### Warnings

Do not receive Enrylaze if:

- you have had a serious allergic reaction to the active ingredient,
  - you have an allergic reaction to any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

- you are currently experiencing serious problems with your pancreas (severe pancreatitis).
- you have experienced serious problems with your pancreas (severe pancreatitis) after being treated with asparaginase therapies.
- you have experienced serious blood clots after being treated with asparaginase therapies.
- you have experienced serious bleeding events after being treated with asparaginase therapies.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

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

**Enrylaze should not be used during pregnancy.** If you are taking Enrylaze and are pregnant, it could hurt the fetus. **Before you start Enrylaze treatment, make sure you are not pregnant.** Talk to your doctor if you are pregnant, think you could be pregnant, or are planning to become pregnant.

**You should not breastfeed during treatment and for two weeks following treatment with Enrylaze, there may be a risk to the feeding child.** Talk to your doctor if you are breastfeeding or intend to breastfeed.

## Fertility & Family planning

**Whether you are a man or woman, you should use contraception and avoid conceiving a child during treatment with Enrylaze and for 3 months after you last receive Enrylaze.** Contraceptives that act through hormones in your bloodstream (such as the oral contraceptive pill) might not work properly if the person taking them is on Enrylaze treatment. Use something else, like condoms.

## 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.

In particular, inform your doctor or pharmacist if you have or are receiving:

- Methotrexate or cytarabine, used in cancer treatment, use of these medicines immediately before Enrylaze may increase their effect.
- Vincristine, which is used in cancer treatment. Use of vincristine with Enrylaze may increase the toxicities of vincristine.
- Glucocorticoids, used as anti-inflammation medicines. Use of these medicines with or immediately before Enrylaze may increase the formation of blood clots.

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

## 4. How will I be given Enrylaze?

### How Enrylaze is given

- Enrylaze can only be initiated by a doctor with experience using medicines to treat cancers.
- Your doctor will determine what dose you are given and whether it will be given to you via an infusion into your veins or an injection into your muscle.
- You may be given some other medicines such as paracetamol or antihistamine before you start receiving Enrylaze to reduce your chances of getting allergic reactions, your doctor will decide whether such premedication is necessary.
- Your doctor will calculate the dose you need. The dose will depend on factors such as your body surface area and response to therapy.
- If you are given Enrylaze into your veins, this will be given over a 2-hour period. If you are given Enrylaze into a muscle, several injection sites may be used.
- Your doctor may decide to discontinue treatment if you experience severe side effects.

### When Enrylaze will be given

- Enrylaze will be given to you according to a treatment schedule. It may be given every 48 hours or on a Monday/Wednesday/Friday schedule. There may be some weeks apart between treatments. Your doctor will decide the best schedule for you.

### If you forget to receive Enrylaze

Let your doctor know as soon as possible if you miss a dose of Enrylaze.

### If you receive too much Enrylaze

If you think that you have been given too much Enrylaze, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using Enrylaze?

### Things you should do

- check with your doctor if you are pregnant or intend to become pregnant.
- check with your doctor if you are breastfeeding or intend to breastfeed. (2.What should I know before I use Enrylaze?)
- always discuss with your doctor any problems during or after treatment with Enrylaze.
- Do not start taking any other medicines, prescription or over-the-counter, without first telling your doctor.

### Call your doctor straight away if you:

- have any of the serious side effects listed in section [6. Are there any side effects?](#)
- Have discomfort or pain in your stomach area. This may be a sign of pancreatitis (inflammation of your pancreas) and should be reported to your doctor straight away.
- have unusual bleeding events or symptoms of blood clots like shortness of breath, chest pain, weakness, trouble speaking etc. If either of these events occur treatment will be paused by your doctor until they are resolved.
- signs of liver toxicity including yellowing of the skin, dark colored urine, itching

Remind any doctor, dentist or pharmacist you visit that you are receiving Enrylaze.

### The following problems may occur during treatment with Enrylaze:

- Serious life endangering allergic reactions. The hospital will ensure they are prepared to address any allergic reaction that may occur during treatment.
- Changes in your body's ability to manage blood sugar levels (hyperglycaemia). Your doctor should monitor your glucose levels whilst on treatment and provide insulin if necessary.
- Issues with your liver. In the event of serious liver toxicity, treatment will be discontinued and supportive care provided. Your doctor will monitor you to identify if you are experiencing any issues with your liver and treat you as necessary.

### Monitoring during treatment with Enrylaze

You will be monitored during and after treatment with Enrylaze for:

- Allergic reactions
- Functions of your pancreas and liver
- Blood sugar levels

## Driving or using machines

Enrylaze can cause you to feel sick and have a headache. This may impact your ability to drive and operate machinery.

## Looking after your medicine

- It is unlikely that you will be asked to store Enrylaze yourself. It will usually be stored in the pharmacy or on the ward.
- Do not use this medicine after the expiry date which is stated on the carton or vial. The expiry date refers to the last day of that month.
- Store the unopened vials in a refrigerator (2°C - 8°C).
- After preparing a dose in a syringe Enrylaze can be stored for up to 8 hours at room temperature (15°C - 25°C) or 24 hours when refrigerated (2°C - 8°C).
- After dilution in an IV bag Enrylaze can be stored for up to 12 hours at room temperature (15°C - 25°C) or 24 hours when refrigerated (2°C - 8°C), starting from when the solution has been withdrawn from the unopened vials.
- Do not use this medicine if you notice any particles in the solution.

Follow the instructions in the carton on how to take care of your medicine properly.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

Your doctor, nurse or pharmacist will dispose of any left-over medicine.

Do not use this medicine after the expiry date.

## 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
<ul style="list-style-type: none"> <li>• <b>allergic reactions</b> including <b>anaphylaxis</b> – may involve rash, itch, hives, hay fever-like symptoms, facial swelling, difficulty breathing, shortness of breath, wheezing, light-headedness, fast heartbeat, sweating, flushing, chills, vomiting or loss of consciousness.</li> <li>• <b>pancreatitis</b> (inflammation of the pancreas) – may involve severe stomach or back pain</li> </ul>	<p><b>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.</b></p>

<ul style="list-style-type: none"> <li>• <b>blood clots</b> including in the brain, neck and extremity veins – may involve pain, swelling, or changes in brain function.</li> <li>• <b>bleeding that won't stop</b></li> <li>• <b>liver toxicity</b> – may involve yellow skin or eyes, sudden weight gain from fluid, or pain in the belly.</li> <li>• <b>infections</b> including blood infection (sepsis)</li> <li>• <b>fever</b></li> </ul>	
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### Other side effects

Other side effects	What to do
<p><b>Head and neurology related:</b></p> <ul style="list-style-type: none"> <li>• fatigue</li> <li>• headache</li> <li>• anxiety</li> <li>• irritability</li> <li>• dizziness</li> </ul> <p><b>Gastrointestinal system related:</b></p> <ul style="list-style-type: none"> <li>• pain in your stomach</li> <li>• diarrhoea</li> <li>• nausea</li> <li>• vomiting</li> <li>• decreased appetite</li> </ul> <p><b>Blood-related:</b></p> <ul style="list-style-type: none"> <li>• low or high blood sugar levels</li> <li>• changes in your blood results, such as low red or white blood cells, low platelets, low albumin, or abnormal clotting</li> <li>• bruising</li> <li>• low blood pressure</li> </ul> <p><b>Other:</b></p> <ul style="list-style-type: none"> <li>• weight loss</li> <li>• pain in limbs</li> <li>• injection site pain or reaction</li> <li>• abnormal kidney function</li> </ul>	<p><b>Speak to your doctor or pharmacist if you have any of these side effects.</b></p>

**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.

### 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](http://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.

### What Enrylaze contains

<b>Active ingredient (main ingredient)</b>	Each vial contains 10mg of recombinant crisantaspase
<b>Other ingredients (inactive ingredients)</b>	Trehalose dihydrate Sodium chloride Sodium hydroxide (pH adjustment) Dibasic sodium phosphate Monobasic sodium phosphate monohydrate Polysorbate 80 Water for injections
<b>Potential allergens</b>	None

**You should not receive this medicine if you have a severe allergy to any of these ingredients.**

### What Enrylaze looks like

Enrylaze is a clear to slightly yellow solution for injection/infusion, free from particulate matter.

One carton contains 3 glass vials, each with a 0.5 mL of solution. (Aust R 423019)

### Who distributes Enrylaze

Jazz Pharmaceuticals ANZ Pty Ltd

Suite 214, Level 2

165 Phillip Street Sydney, NSW, 2000

Australia

Phone: 1800 577 422

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