Fasturtec®

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 Fasturtec?

Fasturtec contains the active ingredient rasburicase. Fasturtec is used to prevent and treat high blood levels of uric acid that may arise from chemotherapy for cancers of the blood such as leukaemia or lymphoma.

For more information, see Section 1. Why am I using Fasturtec? in the full CMI.

2. What should I know before I use Fasturtec?

Do not use if you have ever had an allergic reaction to Fasturtec 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 Fasturtec? in the full CMI.

3. What if I am taking other medicines?

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

For more information, see Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Fasturtec?

- The dose of Fasturtec is calculated according to your body weight. The usual dose is 0.2 mg for each kilogram you weigh.
- Fasturtec is given to you as an infusion into one of your veins (this is called an intravenous infusion).

More instructions can be found in Section 4. How do I use Fasturtec? in the full CMI.

5. What should I know while using Fasturtec?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Fasturtec.
Things you should not do	• Give Fasturtec to anyone else, even if they have the same condition as you. • Use Fasturtec to treat any other complaints unless your doctor tells you to.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how Fasturtec affects you.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Fasturtec will normally be stored in the pharmacy or on the ward. The injection is kept refrigerated (2°C to 8°C). Do not freeze it.

For more information, see Section 5. What should I know while using Fasturtec? in the full CMI.

6. Are there any side effects?

Common side effects: Fever, nausea, vomiting, diarrhoea, headache, skin rash and hives. These side effects can also occur as a result of the chemotherapy medicine you may be receiving.

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.

Fasturtec®

Active ingredient: *rasburicase*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Fasturtec?

Fasturtec contains the active ingredient rasburicase. Fasturtec is a recombinant form of the urate-oxidase enzyme, which converts uric acid into a substance called allantoin that is easier for your kidneys to remove from the body.

Fasturtec is used to prevent and treat high blood levels of uric acid that may arise from chemotherapy for cancers of the blood such as leukaemia or lymphoma.

2. What should I know before I use Fasturtec?

Warnings

Do not use Fasturtec if you:

- are allergic to rasburicase, other uricases 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 a G6PD (glucose-6-phosphate dehydrogenase) deficiency
- have any condition that causes haemolytic anaemia

Check with your doctor if you:

- have a previous history of allergy, asthma, or allergic reactions
- 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

Check with your doctor if you are pregnant or intend to become pregnant. Fasturtec is not recommended for use during pregnancy unless your doctor has discussed the risks and benefits with you.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether Fasturtec passes into breast milk.

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 may interfere with Fasturtec and affect how it works.

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

4. How do I use Fasturtec?

How much to use

- The dose of Fasturtec is calculated according to your body weight. The usual dose is 0.2 mg for each kilogram you weigh. Your doctor may change the dose in some circumstances..

When to use Fasturtec

- Fasturtec is normally given once a day, and may be given for a number of days.

How is Fasturtec given

- Fasturtec is given to you as an infusion into one of your veins (this is called an intravenous infusion).
- The infusion will be given over a 30 minute time span.
- Fasturtec must only be given under supervision of a trained doctor.

If you are given too much Fasturtec (overdose)

Your doctor will decide what dose of Fasturtec you need, and this will be given under close supervision. The risk of an overdose in these circumstances is low. In the event of an overdose, your doctor will decide on the necessary treatment.

Your doctor or pharmacist has information on how to recognise symptoms of an overdose. Ask your doctor or pharmacist if you have any concerns.

5. What should I know while using Fasturtec?

Things you should do

- Tell any other healthcare professionals treating you that you are currently using Fasturtec.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given this medicine.

Call your doctor straight away if you:

- become pregnant while you are taking Fasturtec.

Remind any doctor, dentist or pharmacist you visit that you are using Fasturtec.

Things you should not do

- Give Fasturtec to anyone else, even if they have the same condition as you.
- Use Fasturtec to treat any other complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Fasturtec affects you.

Fasturtec's effect on your ability to drive or operate machinery has not been studied.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol consumption while being treated with Fasturtec has not been studied.

Looking after your medicine

Fasturtec will normally be stored in the pharmacy or on the ward. The injection is kept refrigerated (2°C - 8°C). Do not freeze it.

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

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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.

Less serious side effects

Less serious side effects	What to do
These side effects can also occur as a result of the chemotherapy medicine you may be receiving. • Fever • Nausea • Vomiting • Diarrhoea • Headache • Skin rash • Hives	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• Seizures • Hot flushes • Tightness in the chest • Difficulty in breathing	**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.**

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 in Australia or in New Zealand at https://pophealth.my.site.com/carmreportnz/s/. 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 Fasturtec contains

Active ingredient (main ingredient)	Rasburicase 1.5 mg
Other ingredients (inactive ingredients)	Alanine Mannitol Dibasic sodium phosphate dihydrate Monobasic disodium phosphate Dibasic sodium phosphate dodecahydrate Poloxamer Water for injections

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

What Fasturtec looks like

Fasturtec comes as a clear glass vial containing a white powder, along with an ampoule containing liquid to dissolve the powder. AUST R 80836

Who distributes Fasturtec

Distributed in Australia by:
sanofi-aventis australia pty ltd
International Tower 3, Level 23
300 Barangaroo Avenue
Sydney NSW 2000
Freecall: 1800 818 806
Email: medinfo.australia@sanofi.com

Distributed in New Zealand by:
Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics
PO Box 62027
Sylvia Park Auckland 1644
Freecall: 0800 283 684
Email: medinfo.australia@sanofi.com

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