Fasturtec®

rasburicase

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Fasturtec.

It does not contain all the available information.

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

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you using Fasturtec against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.
You may need to read it again.

What Fasturtec is used for

Fasturtec contains rasburicase rys, which is a recombinant urate-oxidase enzyme. Fasturtec is used to prevent or to decrease the high levels of uric acid in your blood that can occur as a result of chemotherapy for cancers of the blood, such as leukemia or lymphoma. Normal amounts of uric acid in the blood are removed by the kidneys. If there are high levels of uric acid in the blood, your kidneys may not be able to remove the excess, and may be damaged. Fasturtec converts uric acid into a substance called allantoin, which is easier for your kidneys to remove.

Your doctor may have prescribed Fasturtec for another reason.

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

Fasturtec is not addictive.

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

Before you are given Fasturtec

When you must not be given it

You should not be given Fasturtec if you have any of the following conditions:

- G6PD (glucose-6-phosphate dehydrogenase) deficiency
- Any condition that causes haemolytic anaemia

Do not use Fasturtec if you have an allergy to it, other uricases or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to Fasturtec may include skin rash, itchiness, shortness of breath, or difficulty breathing.

Do not use Fasturtec if you are pregnant or intend to become pregnant.
Fasturtec is not recommended for use during pregnancy, unless you and your doctor have discussed the risks and benefits involved.

Do not use Fasturtec if you are breast-feeding or plan to breastfeed.
It is not known whether Fasturtec passes into breast milk.

Do not use Fasturtec after the expiry date (EXP) printed on the pack.
If you use this medicine after the expiry date has passed, it may not work (as well).

Do not use Fasturtec if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using Fasturtec, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.
Your doctor or pharmacist will discuss the possible risks and benefits of using Fasturtec during pregnancy.

Tell your doctor or pharmacist if you are breast-feeding or plan to breastfeed.
Your doctor or pharmacist will discuss the possible risks and benefits of using Fasturtec during breast-feeding.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

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

If you have not told your doctor or pharmacist about any of the above, tell them before you start using Fasturtec.

Taking other medicines

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

Some medicines and Fasturtec may interfere with each other.

Your doctor or pharmacist may have more information on medicines to be careful with or avoid while using Fasturtec.

How Fasturtec is given

How much is given

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

How it is 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 30 minutes. Fasturtec must only be given under the supervision of a trained doctor.

If you are given too much (overdose)

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

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

While you are using Fasturtec

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are using Fasturtec.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are 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.

If you become pregnant while you are being given this medicine, tell your doctor immediately.

Things you must not do

Do not give Fasturtec to anyone else, even if they have the same condition as you.

Do not use Fasturtec to treat any other complaints unless your doctor or pharmacist tells you to.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Fasturtec.

Fasturtec helps most people with high uric acid levels, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

If you get any side effects, do not stop using Fasturtec without first talking to your doctor or pharmacist.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- diarrhoea
- fever
- headache
- nausea
- vomiting
- seizures

These are the most common side effects of Fasturtec. These side effects can also occur as a result of the chemotherapy drugs you may be receiving.

Tell your doctor or pharmacist immediately if you notice any of the following:

- skin rash
- hot flushes
- tightness in the chest
- difficulty in breathing

These may be signs of serious side effects. You may need urgent medical attention. Serious side effects are rare.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Fasturtec

Storage

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

Disposal

If your doctor or pharmacist tells you to stop using Fasturtec or the injections have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

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

Ingredients

Fasturtec 1.5 mg

Active ingredients:

- Each vial contains 1.5 mg rasburicase rys

Other ingredients:

- Alanine
- Mannitol
- Sodium phosphate - dibasic dihydrate
- Disodium phosphate - monobasic
- Sodium phosphate - dibasic dodecahydrate
- Poloxamer
- Water for injections

There are three ampoules and three vials in a carton.

Fasturtec 7.5 mg

Active ingredients:

- Each vial contains 7.5 mg rasburicase rys

Other ingredients:

- Alanine
- Mannitol
- Sodium phosphate - dibasic dihydrate
- Disodium phosphate - monobasic
- Sodium phosphate - dibasic dodecahydrate
- Poloxamer
- Water for injections

There is one ampoule and one vial in a carton.

Manufacturer

Fasturtec is supplied in Australia by:

Sanofi-Aventis Australia Pty Ltd
12-24 Talavera Road
Macquarie Park
NSW 2113
Australia

Fasturtec 1.5 mg/mL has the Registration No: AUST R 80836

Fasturtec 7.5 mg/mL has the Registration No: AUST R 93860

Fasturtec is supplied in New Zealand by:

Sanofi-Aventis New Zealand Limited
Level 8,
56 Cawley Street
Ellerslie
Auckland

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