READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Pr FASTURTEC®
(rasburicase)

Powder for Injection
Professed Standard

1.5 mg/vial

Read this carefully before you start taking FASTURTEC and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about FASTURTEC.

Serious Warnings and Precautions

- Allergic reactions: FASTURTEC can cause serious allergic reactions, which may be fatal. If allergic reactions develop, your doctor will immediately and permanently discontinue treatment with FASTURTEC.
- You should not be given FASTURTEC if you have a disease called glucose-6-phosphate dehydrogenase deficiency (G6PD deficiency). Your doctor will decide if you should be tested before treatment.
- You should not be given FASTURTEC if you have a history of hemolysis (disorder of the blood in which red blood cells are abnormally broken down). If hemolysis or methemoglobinemia (disease caused by abnormal blood pigment levels) develop during treatment, your doctor will immediately and permanently discontinue FASTURTEC.

What is FASTURTEC used for?

FASTURTEC is used to treat or prevent high blood levels of uric acid from occurring in adults and children with cancer who are about to receive or are receiving chemotherapy treatment.

How does FASTURTEC work?

When chemotherapy is given, cancer cells are destroyed, releasing large amounts of uric acid into the bloodstream.

FASTURTEC works by allowing uric acid to be more easily removed from the body by the kidneys.

What are the ingredients in FASTURTEC?

Medicinal ingredients: rasburicase
Non-medicinal ingredients: L-alanine, disodium phosphate dodecahydrate, mannitol.
The solvent for rasburicase powder contains sterile water for injection and poloxamer 188.

FASTURTEC comes in the following dosage forms:

FASTURTEC comes as a clear glass vial with a rubber stop containing a white to off-white powder, along with an ampoule containing a clear and colorless liquid to dissolve the powder.

FASTURTEC is provided in a box containing:

- 3 vials of 1.5 mg rasburicase and 3 ampoules of 1 ml solvent.

Do not use FASTURTEC if:

- you are allergic (hypersensitive) to rasburicase, to other uricases or to any of the other ingredients of this medicine (see section above: What are the ingredients in Fasturtec?)
- you have a disease called glucose-6-phosphate dehydrogenase deficiency (G6PD deficiency), also known as favism
- you have a history of hemolytic anemia (an illness caused by red blood cells being abnormally broken down).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take FASTURTEC. Talk about any health conditions or problems you may have, including if you:

- have a history of any kind of allergy. Tell your doctor if you have ever had any allergic type reactions due to other medicines, as FASTURTEC can cause allergic-type reactions, including severe cases. It is not known whether the chance of developing an allergic reaction is increased if treatment with FASTURTEC is repeated.
- are, or think you may be pregnant
- are breastfeeding, or intend to breastfeed.

Other warnings you should know about:

During treatment with FASTURTEC, your doctor will carry out blood tests to check the levels of uric acid and decide how long you will be treated for.

Your doctor may also test your blood to make sure that you do not develop any blood disorders.

In case disorders of the blood in which red blood cells are abnormally broken down (hemolysis) or abnormal blood pigment levels occur (methemoglobinemia), your doctor will immediately and permanently discontinue treatment with FASTURTEC.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take FASTURTEC:

FASTURTEC is to be given to you before or during the start of your course of chemotherapy.

FASTURTEC is injected slowly into a vein, which should take about 30 minutes.

Usual dose:

Your dose will be calculated according to your body weight.

The recommended dose is 0.20 mg per kg of body weight per day in both children and adults. It will be given once a day, for up to 7 days.

Overdose:

If an overdose does occur, your doctor will closely monitor the effects on your red blood cells and treat any symptoms that follow.

If you have any further questions on the use of this medicine, ask your doctor, nurse or hospital pharmacist.

If you think you have taken too much FASTURTEC, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

What are possible side effects from using FASTURTEC?

Like all medicines, this medicine can cause side effects, although not everybody gets them. FASTURTEC will be administered at the same time as other medicines that may also cause side effects.

These are not all the possible side effects you may feel when taking FASTURTEC. If you experience any side effects not listed here, contact your healthcare professional.

Tell your doctor, nurse or hospital pharmacist immediately if you suddenly notice the following symptoms, as these may be signs of a serious allergic reaction (anaphylaxis):

- a swelling of the face, lips, tongue or other part of your body
- a shortness of breath, wheezing or breathing problems
- a rash, itching or hives.

Very common side effects (may affect more than 1 in 10 people):

- diarrhea
- vomiting
- nausea

- headache
- fever
- allergic reactions, mainly rashes and urticaria.

Frequency not known (frequency cannot be estimated from the available data):

- severe hypersensitivity reactions, including anaphylaxis
- low blood pressure (hypotension)
- wheezing or difficulty in breathing (bronchospasm)
- runny or blocked nose, sneezing, facial pressure or pain (rhinitis)
- blood disorders such as a disorder of the blood in which red blood cells are abnormally broken down (hemolytic anemia), or disorders with abnormal blood pigment levels (methemoglobinemia)
- involuntary muscle movements/contraction
- convulsions.

If you notice any of these, tell your doctor, nurse or hospital pharmacist.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE Severe hypersensitivity reactions, with symptoms such as: swelling of the face, lips, tongue or other part of your body; shortness of breath, wheezing or breathing problems; rash, itching or hives.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects
You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.
3 ways to report:

- Online at MedEffect;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 0701E
    Ottawa, ON
    K1A 0K9

    Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton.

This medicine should be stored in a refrigerator (2°C – 8°C). Do not freeze.

Store in the original package in order to protect from light.

Do not use this medicine if you notice that the solution is unclear and/or contains particles.

If you want more information about FASTURTEC:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the manufacturer's website www.sanofi.ca, or by calling 1-800-265-7927.

This leaflet was prepared by Sanofi-aventis Canada Inc.

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