Package leaflet:
Information for the user

sanofi

FASTURTEC® 1.5 mg/ml

powder and solvent for concentrate for solution for infusion

rasburicase

Is this leaflet hard to see or read? Phone 0800 035 2525 for help.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or hospital pharmacist.
- If you get any side effects, please talk to your doctor, nurse or hospital pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fasturtec is and what it is used for

Fasturtec contains the active ingredient rasburicase.
Rasburicase is used to treat or prevent high blood levels of uric acid from occurring in adults, children and adolescents (aged 0 to 17 years) with disorders of the blood cells (haematological diseases) who are about to receive or are receiving chemotherapy treatment.
When chemotherapy is given, cancer cells are destroyed, releasing large amounts of uric acid into the bloodstream.
Fasturtec works by allowing uric acid to more easily be removed from the body by the kidneys.

2. What you need to know before you are given Fasturtec

Do not use Fasturtec if you:

- are **allergic** (hypersensitive) to rasburicase, other uricases or any of the other ingredients of this medicine (listed in section 6).
- have a history of **haemolytic anaemia** (an illness caused by red blood cells being abnormally broken down).

Warning and precautions

Talk to your doctor, nurse or hospital pharmacist 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; Fasturtec can cause allergic-type reactions, such as severe anaphylaxis including anaphylactic shock (sudden life-threatening or fatal allergic reactions).
Tell your doctor immediately if you notice any of the following as you may need to stop treatment:

- swelling of the face, lips, tongue or throat
- coughing or wheezing
- difficulty in breathing or swallowing
- rash, itching or hives (nettle-type rash) on the skin

These may be the first signs that a **severe allergic reaction** is happening. Your treatment with Fasturtec may need to be stopped, and you may need further treatment.
It is not known whether the chance of developing an allergic reaction is increased if treatment with Fasturtec is repeated.
In case of disorders of the blood in which red blood cells are abnormally broken down (haemolysis) or abnormal blood pigment levels (methaemoglobinaemia), your doctor will immediately and permanently discontinue treatment with Fasturtec.

Other medicines and Fasturtec

Please tell your doctor if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Tell your doctor if you are, or think you may be pregnant, or if you are breast-feeding.

Driving and using machines

No information on the ability to drive and use machines is available.

Fasturtec contains sodium

This medicine contains up to 10.5 mg sodium, (main component of cooking/table salt) per vial. This is equivalent to 0.53% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use 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.
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. 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.

If you are given more Fasturtec than you should be

If it does occur, the 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.

4. Possible side effects

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.

If you suddenly notice:

- 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

Tell your doctor, nurse or hospital pharmacist immediately as these may be signs of a serious allergic reaction (anaphylaxis). These are rare (may affect up to 1 in 1,000 people).

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

- diarrhoea
- vomiting
- nausea
- headache
- fever

Common side effects (may affect up to 1 in 10 people):

- allergic reactions, mainly rashes and urticaria.

Uncommon side effects (may affect up to 1 in 100 people):

- severe hypersensitivity reactions, such as anaphylaxis (rare) including anaphylactic shock (frequency not known) which may be fatal
- low blood pressure (hypotension)
- wheezing or difficulty in breathing (bronchospasm)
- blood disorders such as a disorder of the blood in which red blood cells are abnormally broken down (haemolysis), destroyed (haemolytic anaemia), or abnormal blood pigment levels (methaemoglobinaemia)
- fits (convulsion).

Rare (may affect up to 1 in 1,000 people):
- runny or blocked nose, sneezing, facial pressure or pain (rhinitis).

Frequency not known (frequency cannot be estimated from the available data)
- involuntary muscle movements (muscle contraction involuntary).

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

Reporting of side effects
If you get any side effects, talk to your doctor, nurse or hospital pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fasturtec

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 after EXP. The expiry date refers to the last day of that month.
Store 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.

6. Contents of the pack and other information

What Fasturtec contains
- The active substance is rasburicase 1.5 mg/ml. Rasburicase is produced by genetechnology in a microorganism named *Saccharomyces cerevisiae*.
- The other ingredients of the powder are: alanine, mannitol, disodium phosphate dodecahydrate, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate.
- The other ingredients of the solvent are: poloxamer 188, water for injection.

What Fasturtec looks like and contents of the pack
Fasturtec is provided as a powder for concentrate for solution for infusion (powder for sterile concentrate) with a solvent.
The powder is an entire or broken white to off white pellet.
The solvent is a colourless and clear liquid.
Pack of 3 vials of 1.5 mg rasburicase and 3 ampoules of 1 ml solvent. The powder is supplied in 2 ml or 3 ml clear glass vial with a rubber stopper and the solvent in a 2 ml clear glass ampoule.
Pack of 1 vial of 7.5 mg rasburicase and 1 ampoule of 5 ml solvent. The powder is supplied in 10 ml clear glass vial with a rubber stopper and the solvent in a 5 ml clear glass ampoule.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Sanofi
410 Thames Valley Park Drive
Reading
Berkshire
RG6 1PT
UK
Tel: 0800 035 2525
email:
uk-medicalinformation@sanofi.com
Manufacturers
Sanofi S.r.l.
Via Valcanello, 4
03012 Anagni (FR)
Italy

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in November 2022.

The following information is intended for healthcare professionals only:
See section 3 "How to use Fasturtec" and practical information on preparation and handling given below.
Fasturtec must be reconstituted with the entire volume of the supplied solvent (e.g. 1.5 mg rasburicase vial to be reconstituted with the 1 ml solvent ampoule; 7.5 mg rasburicase vial to be reconstituted with the 5 ml solvent ampoule). Reconstitution results in a solution with a concentration of 1.5 mg/ml to be further diluted with sodium chloride 9 mg/ml (0.9%).

Reconstitution of the solution:
Add the content of one ampoule of solvent to one vial containing rasburicase and mix by swirling very gently under controlled and validated aseptic conditions.
Do not shake.
Inspect visually prior to use. Only clear and colourless solutions without particles should be used.
For single-use only, any unused solution should be discarded.
The solvent contains no preservative. Therefore the reconstituted solution should be diluted under controlled and validated aseptic conditions.

Dilution before infusion:
The required volume of the reconstituted solution depends on the patient's body weight. The use of several vials may be necessary to obtain the quantity of rasburicase required for one administration.
The required volume of the reconstituted solution, taken from one or more vials, is to be further diluted with sodium chloride 9 mg/ml (0.9%) solution to make a total volume of 50 ml.
The concentration of rasburicase in the final solution for infusion depends on the patient's body weight.
The reconstituted solution contains no preservative. Therefore the diluted solution should be infused immediately.

Infusion:
The final solution should be infused over 30 minutes.

Sample handling:
If it is necessary to monitor a patient's uric acid level, a strict sample-handling procedure must be followed to minimise *ex vivo* degradation of the analyte. Blood must be collected into pre-chilled tubes containing heparin anticoagulant. Samples must be immersed in an ice/water bath. Plasma samples should immediately be prepared by centrifugation in a pre-cooled centrifuge (4°C). Finally, plasma must be maintained in an ice/water bath and analysed for uric acid within 4 hours.

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