EMA/270684/2015
EMEA/H/C/000331

EPAR summary for the public

Fasturtec

rasburicase

This is a summary of the European public assessment report (EPAR) for Fasturtec. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Fasturtec.

What is Fasturtec?

Fasturtec is a medicine that contains the active substance rasburicase. It is available as a powder and solvent that are made up into a solution for infusion (drip) into a vein.

What is Fasturtec used for?

Fasturtec is used to treat and prevent high levels of uric acid in the blood in order to prevent kidney failure. It is used in adults and children with blood cancers who are at risk of a sudden rise in uric acid levels when they start to receive chemotherapy (medicines to treat cancer).

The medicine can only be obtained with a prescription.

How is Fasturtec used?

Fasturtec treatment should be supervised by a doctor who has been trained in the use of chemotherapy for blood cancers. Fasturtec is given immediately before or during the start of chemotherapy. The recommended dose is 0.2 mg per kilogram body weight in both children and adults, given as a daily infusion for up to seven days. The duration of treatment is adjusted depending on the patient's blood levels of uric acid and the doctor's judgment. The infusion should last 30 minutes.

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How does Fasturtec work?

Uric acid is a by-product of the breakdown of cells. Patients undergoing chemotherapy may be at risk of rapid tumour lysis, where many cancer cells are broken down at once causing a sudden rise of uric acid in the blood which can cause damage to the kidneys.

The active substance in Fasturtec, rasburicase, is an enzyme called urate oxidase, which transforms uric acid into another chemical called allantoin, which can easily be excreted by the kidneys in the urine. This helps to reduce the levels of uric acid in the blood, thereby reducing the load on the kidney and preventing any damage. The enzyme was originally extracted from a fungus, but in Fasturtec it is produced by a method known as 'recombinant DNA technology': it is made by a yeast into which a gene (DNA) has been introduced that makes it able to produce urate oxidase.

How has Fasturtec been studied?

The benefits of Fasturtec were first studied in three main studies involving a total of 293 patients, including adults and children. Two of the studies were designed to define the best dose to use. Fasturtec was only compared with another treatment (allopurinol, the standard treatment for reducing uric acid levels) in one of the studies, which included 52 patients.

An additional study looked at the effects of Fasturtec in 21 children (aged between 6 months and 16 years) with blood cancers of whom 62% had uric acid levels that were too high. Fasturtec was not compared with another medicine in this study.

The main measures of effectiveness were based on the reduction in blood uric acid levels.

What benefit has Fasturtec shown during the studies?

The dose-finding studies showed that, after 48 hours, Fasturtec at a daily dose of 0.2 mg per kg reduced the uric acid levels to normal in 95% of patients. In the comparative study, Fasturtec was more effective than allopurinol: over the first 96 hours after treatment, patients treated with Fasturtec had a lower average blood level of uric acid than the patients treated with allopurinol (128.1 and 328.5 mg.h/dl, respectively).

In the additional study, none of the 21 children treated with Fasturtec had high uric acid levels after 24 or 48 hours. This study also showed improvement in kidney function.

What is the risk associated with Fasturtec?

The most common side effects with Fasturtec (seen in more than 1 patient in 10) are nausea (feeling sick), vomiting, headache, fever and diarrhoea. For the full list of all side effects reported with Fasturtec, see the package leaflet.

Fasturtec must not be used in patients with a deficiency in (low levels of) glucose 6 phosphate dehydrogenase (G6PD) or other metabolic disorders known to cause haemolytic anaemia (low haemoglobin levels caused by the abnormal breakdown of red blood cells). For the full list of restrictions, see the package leaflet.

Why has Fasturtec been approved?

The CHMP decided that Fasturtec's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Fasturtec

The European Commission granted a marketing authorisation valid throughout the European Union for Fasturtec on 23 February 2001.

The full EPAR for Fasturtec can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Fasturtec, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2015.