EMA/814820/2018
EMEA/H/C/003789

Oncaspar (*pegaspargase*)

An overview of Oncaspar and why it is authorised in the EU

What is Oncaspar and what is it used for?

Oncaspar is a cancer medicine used in adults and children to treat acute lymphoblastic leukaemia (ALL), a cancer of white blood cells called lymphoblasts. Oncaspar is used in combination with other cancer medicines.

It contains the active substance pegaspargase.

How is Oncaspar used?

Oncaspar is normally given every 14 days by injection into a muscle or by infusion (drip) into a vein, with the dose depending on age and body surface area.

Oncaspar can only be obtained with a prescription and only healthcare professionals with experience of cancer treatments should prescribe and give the medicine. The healthcare professional should give the medicine in a hospital where resuscitation equipment is available.

For more information about using Oncaspar, see the package leaflet or contact your doctor or pharmacist.

How does Oncaspar work?

The active substance (pegaspargase) contains the enzyme asparaginase which works by breaking up and reducing the blood levels of the amino acid asparagine. The cancer cells need this amino acid to grow and multiply, and so its reduction in the blood causes the cells to die. Normal cells, by contrast, can produce their own asparagine and are less affected by the medicine.

The asparaginase enzyme in this medicine is linked to a chemical which slows down its removal from the body and can reduce the risk of allergic reactions.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

What benefits of Oncaspar have been shown in studies?

In a study in 118 children newly diagnosed with ALL, 75% of those treated with Oncaspar (in combination with other medicines) were free of the cancer after 7 years, without having relapse or a new cancer during that period. This compares with 66% of those treated with another asparaginase.

In another study of 76 children whose cancer returned after earlier treatment, around 40% of Oncaspar-treated patients (some of whom were allergic to other asparaginase treatments) were cleared of the cancer, compared with 47% of patients treated with an asparaginase comparator.

What are the risks associated with Oncaspar?

The most common side effects with Oncaspar (which may affect more than 1 in 10 people) include signs of liver problems (raised levels of liver enzymes and bilirubin in the blood), reduced blood clotting, high levels of fats in the blood, high levels of blood glucose and low levels of white blood cells accompanied by fever. For the full list of side effects of Oncaspar, see the package leaflet.

Oncaspar must not be used in patients with severe liver disease, patients who have ever had pancreatitis (including pancreatitis caused by previous asparaginase treatments) or patients who have had severe bleeding or serious blood clots following asparaginase treatment. For the full list of restrictions, see the package leaflet.

Why is Oncaspar authorised in the EU?

Studies showed Oncaspar to be effective in patients with ALL, including patients who were allergic to asparaginase. Oncaspar also comes with the advantage of requiring fewer injections as the medicine stays longer in the body than some other asparaginases. However, the data in adult patients were limited and the company that markets the medicine is to provide further data of its benefit in this group of patients.

As for its risks, the side effects of Oncaspar are similar to those of other asparaginase medicines and are considered manageable

The European Medicines Agency therefore decided that Oncaspar's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Oncaspar?

The company that markets Oncaspar will complete two more studies on the safety and effectiveness of Oncaspar, which will help further clarify the benefits and risks of this medicine in adults and in newly diagnosed patients.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Oncaspar have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Oncaspar are continuously monitored. Side effects reported with Oncaspar are carefully evaluated and any necessary action taken to protect patients.

Other information about Oncaspar

Oncaspar received a marketing authorisation valid throughout the EU on 14 January 2016.

Further information on Oncaspar can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR Oncaspar.

This overview was last updated in 11-2018.