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Enrylaze (*crisantaspase*)

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

What is Enrylaze and what is it used for?

Enrylaze is a cancer medicine used in adults and children aged one month and older to treat acute lymphoblastic leukaemia (ALL) and lymphoblastic lymphoma (LBL), cancers of white blood cells called lymphoblasts. It is used in combination with other medicines in patients who have developed hypersensitivity (allergic reactions) or silent inactivation to *E. coli*-derived asparaginase, another cancer medicine. Silent inactivation means development of antibodies (proteins) that reduce the effectiveness of asparaginase without resulting in apparent allergy symptoms.

Enrylaze contains the active substance crisantaspase.

How is Enrylaze used?

The medicine can only be obtained with a prescription and should be prescribed and given by doctors and healthcare professionals experienced in the use of cancer treatments, in a setting with appropriate medical support and resuscitation equipment to treat anaphylaxis (a sudden, severe allergic reaction).

Enrylaze is given as an infusion (drip) into a vein or as an injection into a muscle, either every two days or three times each week. The dose depends on the patient's body surface area and the frequency of dosing.

To reduce the risk of infusion-related reactions, patients may be given other medicines before treatment with Enrylaze.

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

How does Enrylaze work?

The active substance in Enrylaze, crisantaspase, is an enzyme (protein) that 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.

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What benefits of Enrylaze have been shown in studies?

The benefits of Enrylaze were evaluated in a study involving adults and children with ALL or LBL who had developed hypersensitivity or silent inactivation following use of *E. coli*-derived asparaginase. The study did not compare Enrylaze with other medicines or placebo (a dummy treatment).

In this study, 90% (44 out of 49) of patients given Enrylaze by injection achieved nadir serum asparaginase activity (NSAA) levels ≥ 0.1 U/mL (a measure corresponding to the complete depletion of blood asparagine) after 72 hours of receiving a first course of treatment; 96% (47 out of 49) achieved NSAA levels ≥ 0.1 U/mL after 48 hours.

For those patients given Enrylaze by infusion, 40% (20 out of 50) achieved NSAA levels ≥ 0.1 U/mL after 72 hours of receiving a first course of treatment; 90% (53 out of 59) achieved NSAA levels ≥ 0.1 U/mL after 48 hours.

What are the risks associated with Enrylaze?

For the full list of side effects and restrictions with Enrylaze, see the package leaflet.

The most common side effects with Enrylaze (which may affect more than 1 in 10 people) include anaemia (low levels of red blood cells), vomiting, thrombocytopenia (low levels of blood platelets, components that help the blood to clot), neutropenia (low levels of neutrophils, a type of white blood cell), nausea, febrile neutropenia (low levels of neutrophils with fever), fatigue, pyrexia (fever), decreased appetite, increased blood levels of liver enzymes called transaminases, abdominal (belly) pain, decreased levels of white blood cells, headache, diarrhoea and decreased levels of lymphocytes (a type of white blood cell).

The most common serious side effects include febrile neutropenia, pyrexia, vomiting, sepsis (blood poisoning), hypersensitivity to asparaginase, nausea and pancreatitis (inflammation of the pancreas).

Enrylaze must not be used in patients who have severe pancreatitis. It must also not be used in patients who have ever had severe pancreatitis, bleeding or blood clots following asparaginase treatment.

Why is Enrylaze authorised in the EU?

Enrylaze is effective at reducing blood asparagine levels in patients with ALL and LBL who have developed hypersensitivity or silent inactivation following use of *E. coli*-derived asparaginase, a group of patients for whom limited treatment options exist. While those treated by infusion had a lower response rate compared to those treated by injection, the response was still sufficient for a proportion of the patients. Furthermore, EMA recommended that asparaginase levels are monitored in all patients. If the targeted asparaginase activity level is not achieved, it is proposed to switch to an alternative dosing regimen. The side effects of Enrylaze are similar to those of other asparaginase medicines and are considered manageable.

The European Medicines Agency decided that Enrylaze'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 Enrylaze?

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

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

Other information about Enrylaze

Enrylaze received a marketing authorisation valid throughout the EU on 15 September 2023.

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

This overview was last updated in 09-2023.