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EPAR summary for the public

Spectrila

asparaginase

This is a summary of the European public assessment report (EPAR) for Spectrila. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Spectrila.

For practical information about using Spectrila, patients should read the package leaflet or contact their doctor or pharmacist.

What is Spectrila and what is it used for?

Spectrila is used in adults and children to treat acute lymphoblastic leukaemia (ALL), a cancer of white blood cells called lymphoblasts, in combination with other cancer medicines. It contains the active substance asparaginase.

How is Spectrila used?

Spectrila is given every 3 days by infusion (drip) into a vein, with the dose depending on the patient's age and body surface area.

Only healthcare professionals experienced in cancer treatments should prescribe and give Spectrila. The healthcare professional should only give the medicine in a hospital setting where resuscitation equipment is available. For further information, see the package leaflet.

Spectrila can only be obtained with a prescription and is available in a vial as a powder to be made into a solution for infusion.

How does Spectrila work?

The active substance in Spectrila, asparaginase, is an enzyme 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

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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.

What benefits of Spectrila have been shown in studies?

In a study in 199 children with ALL, Spectrila was as effective as another asparaginase medicine (both used in combination with other medicines) in reducing blood asparagine: 95% of patients treated with Spectrila and 94% of those treated with the other medicine containing asparaginase had complete depletion (reduction) of blood asparagine.

What are the risks associated with Spectrila?

The most common side effects with Spectrila (which may affect more than 1 in 10 people) are allergic reactions (including flushing, rash, low blood pressure, hives and difficulty breathing), diarrhoea, nausea, vomiting, abdominal pain, tiredness, swelling (caused by fluid build-up), high blood sugar, and low blood levels of albumin (a protein) and other abnormalities in blood tests. For the full list of side effects reported with Spectrila, see the package leaflet.

The most serious side effects with Spectrila include severe allergic reactions, blood clots, pancreatitis (inflammation of the pancreas), and liver problems.

Spectrila must not be used in patients who are allergic to any asparaginase preparation and those who have pancreatitis (inflammation of the pancreas), severe liver disease or blood clotting problems. It must also not be used in patients who have ever had pancreatitis, or severe bleeding or blood clots following asparaginase treatment. For the full list of restrictions, see the package leaflet.

Why is Spectrila approved?

Spectrila is effective at reducing blood asparagine that the cancer cells need to survive. Although the data in adults are limited, there is substantial clinical experience of asparaginase medicines in adults, and the benefits of Spectrila in adults can be expected to be similar.

As for its risks, the side effects of Spectrila are similar to those of other asparaginase medicines and are addressed in the medicine's risk minimisation plan.

The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore concluded that the benefits of Spectrila are greater than the risks and recommended that it be approved for use in the EU.

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

A risk management plan has been developed to ensure that Spectrila is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Spectrila, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Spectrila

The European Commission granted a marketing authorisation valid throughout the European Union for Spectrila on 14 January 2016.

The full EPAR and risk management plan summary for Spectrila 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 Spectrila, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2016.