European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

LITAK

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Litak?
Litak is a solution for injection that contains the active substance cladribine.

What is Litak used for?
Litak is used to treat adults with hairy cell leukaemia, a cancer of blood in which too many B-lymphocytes (a type of white blood cell) are produced. The term 'hairy cell' refers to the hair-like projections that can be seen on the surface of the lymphocytes when they are examined under a microscope.
Because the number of patients with hairy cell leukaemia is low, the disease is considered 'rare', and Litak was designated an 'orphan medicine' (a medicine used in rare diseases) on 18 September 2001.
The medicine can only be obtained with a prescription.

How is Litak used?
Litak treatment should be started by a doctor who has experience in the use of cancer treatments. Litak is given as an injection under the skin. The recommended dose is 0.14 mg per kilogram body weight, once a day for five days. Patients can inject themselves once they have been trained appropriately.
Litak must not be given to patients with moderate to severe liver or kidney disease. It should be used with caution in patients over 65 years of age, with frequent monitoring of blood counts, the liver and the kidneys.

How does Litak work?
The active substance in Litak, cladribine, is a cytotoxic, a medicine that kills cells that are dividing, such as cancer cells. It belongs to the group of anticancer medicines called 'antimetabolites'.
Cladribine is an 'analogue' of purine (a substance that has a similar chemical structure to purine). Purine is one of the fundamental chemicals that make up DNA. In the body, cladribine is converted within lymphocytes into a chemical called CdATP, which interferes with the production of new DNA. This prevents the cells from dividing, slowing down the progression of leukaemia. CdATP can also affect other cells, particularly other types of blood cell, which can cause side effects.
Cladribine has been in use in anticancer medicines since the 1980s and it has been available as an intravenous infusion (drip into a vein) in some European Union (EU) Member States since 1993.

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How has Litak been studied?
Because cladribine has been used for a number of years, the company presented data from the published literature. Litak has been examined in one main study involving 63 adults with hairy cell leukaemia. Litak was not compared with any other treatments in this study. The main measures of effectiveness were the numbers of patients who had complete and partial remission following treatment. Complete remission is the disappearance of all evidence of disease, whereas partial remission is improved blood counts and the reduction in the number of cancerous cells.

What benefit has Litak shown during the studies?
In the main study, 97% of the patients had either complete or partial remission (60 out of 62), and 76% had complete remission (47 out of 62). These results were similar to those seen in other published studies using intravenous cladribine and were better than results seen with alternative treatments such as interferon alfa and pentostatin.

What is the risk associated with Litak?
The most common side effects with Litak (seen in more than 1 patient in 10) are infections, pancytopenia or myelosuppression (low blood cell counts), purpura (bruising), immunosuppression (a weakened immune system), decreased appetite, headache, dizziness, abnormal breath and chest sounds, cough, nausea (feeling sick), vomiting, constipation, diarrhoea, rash, localised exanthema (skin eruptions), diaphoresis (excessive sweating), injection site reactions (pain and inflammation at the site of injection), fever, fatigue (tiredness), chills and asthenia (weakness). For the full list of all side effects reported with Litak, see the Package Leaflet.
Litak should not be used in people who may be hypersensitive (allergic) to cladribine or any of the other ingredients. Litak must not be used during pregnancy or breast-feeding, in patients less than 18 years of age, in patients with moderate to severe kidney or liver disease or in combination with other medicines that reduce the production of blood cells.

Why has Litak been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Litak's benefits are greater than its risks for the treatment of hairy cell leukaemia. The Committee recommended that Litak be given marketing authorisation.

Other information about Litak:
The European Commission granted a marketing authorisation valid throughout the EU for Litak to Lipomed GmbH on 14 April 2004. The marketing authorisation was renewed on 14 April 2009.

The summary of opinion of the Committee for Orphan Medicinal Products for Litak is available here.
The full EPAR for Litak can be found here.

This summary was last updated in 04-2009.