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EPAR summary for the public

DepoCyte

cytarabine

This document is a summary of the European Public Assessment Report (EPAR) for DepoCyte. 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 DepoCyte.

What is DepoCyte?

DepoCyte is a suspension for injection that contains 50 mg of the active substance, cytarabine.

What is DepoCyte used for?

DepoCyte is used to treat lymphomatous meningitis. This is a condition in which cells from a lymphoma (a tumour in the lymphatic system) have spread to the spinal fluid and the meninges (the membranes that surround the brain and spinal cord). DepoCyte helps to control the symptoms of the disease. These symptoms mainly affect the nerves, and include pain, fits, headache, problems walking, memory problems, incontinence and unusual sensations.

The medicine can only be obtained with a prescription.

How is DepoCyte used?

DepoCyte should only be given by a doctor who has experience in the use of anticancer medicines.

DepoCyte is a 'depot' injection (a type of injection where the medicine is prepared so that it is absorbed by the body very slowly). The medicine must be injected 'intrathecally' (directly into the spinal fluid in the space that surrounds the spinal cord and the brain). The patient should also receive dexamethasone (a steroid) to help control some of the medicine's side effects.

DepoCyte is first given as a 50-mg injection every two weeks for the first five doses, followed by a further 50 mg four weeks later. This is then followed by maintenance doses of 50 mg every four weeks

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for a further four doses. The dose can be decreased to 25 mg if the patient shows signs of damage to the nerves (such as headache, abnormal vision, muscle weakness or pain).

How does DepoCyte work?

The active substance in DepoCyte, cytarabine (also known as ara-C), is an anticancer medicine that has been used since the 1970s. It is a cytotoxic (a medicine that kills cells that are dividing, such as cancer cells), which belongs to the 'anti-metabolite' group.

Cytarabine is an analogue of pyrimidine. Pyrimidine is part of the genetic material of cells (DNA and RNA). In the body, cytarabine takes the place of pyrimidine and interferes with the enzymes involved in the production of new DNA. As a result, cytarabine slows down the growth of tumour cells and eventually kills them. In DepoCyte, cytarabine is contained in liposomes (small fatty particles), from which the medicine is released slowly.

How has DepoCyte been studied?

DepoCyte has been compared with a standard formulation of cytarabine in one main study involving 35 patients with lymphomatous meningitis. The main measure of effectiveness was the number of patients who responded to treatment. A patient was classified as a 'responder' if they had no cancer cells in the spinal fluid after treatment and if their symptoms had not got worse after four weeks. The study also looked at how long the patients lived without their nerve disease getting worse.

What benefit has DepoCyte shown during the studies?

In the main study, 72% of the patients who received DepoCyte responded to treatment (13 out of 18), compared with 18% of those who received the standard formulation of cytarabine (3 out of 17). However, there was no difference between the two medicines in how long the patients lived without their nerve disease getting worse.

What is the risk associated with DepoCyte?

The most common side effects with DepoCyte (seen in more than 1 treatment cycle in 10) are headache, arachnoiditis (inflammation of one of the membranes protecting the spine and the brain), confusion, nausea (feeling sick), vomiting, diarrhoea, pyrexia (fever), weakness and thrombocytopenia (low blood platelet counts).To minimise the symptoms of arachnoiditis, patients should receive dexamethasone by mouth or by injection at the same time as DepoCyte and must be closely monitored. For the full list of all side effects reported with DepoCyte, see the Package Leaflet.

DepoCyte should not be given to people who may be hypersensitive (allergic) to cytarabine or any of the other ingredients. It must not be used in patients who have an active infection in the meninges.

Why has DepoCyte been approved?

The CHMP noted that DepoCyte had shown effectiveness in lymphomatous meningitis when compared with the standard formulation of cytarabine, and that it could improve patients' quality of life because fewer intrathecal injections are needed. The Committee decided that DepoCyte's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about DepoCyte:

The European Commission granted a marketing authorisation valid throughout the European Union for DepoCyte on 11 July 2001. The marketing authorisation holder is Pacira Limited. The marketing authorisation is valid for an unlimited period.

The full EPAR for DepoCyte can be found here. For more information about treatment with DepoCyte, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2011.