



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/585593/2013
EMA/H/C/802

EPAR summary for the public

Mepact

mifamurtide

This document is a summary of the European public assessment report (EPAR) for Mepact. 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 Mepact.

What is Mepact?

Mepact is a powder that is made up into a suspension for infusion (drip into a vein). It contains the active substance mifamurtide.

What is Mepact used for?

Mepact is used to treat high-grade non-metastatic osteosarcoma (a type of bone cancer) in patients aged between two and 30 years. 'High grade' means that the cancer is of a severe type, and 'non-metastatic' means that it is at an early stage and has not spread far within the body. Mepact is used with other anticancer medicines after the cancer has been removed by surgery.

Because the number of patients with osteosarcoma is low, the disease is considered 'rare', and Mepact was designated an 'orphan medicine' (a medicine used in rare diseases) on 21 June 2004.

The medicine can only be obtained with a prescription.

How is Mepact used?

Mepact treatment should be started and supervised by a specialised doctor who has experience in diagnosing and treating osteosarcoma.

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The dose of Mepact depends on the patient's height and weight. It should be given twice a week for 12 weeks, and then once a week for 24 weeks. Mepact is given as a slow infusion lasting an hour. It must not be given as a bolus injection (all at once).

How does Mepact work?

The active substance in Mepact, mifamurtide, is an immunomodulator. It works by activating macrophages and monocytes (types of white blood cell that form part of the immune system). The precise way that mifamurtide works in osteosarcoma is not fully understood, but it is thought to cause the white blood cells to release chemicals that kill the cancerous cells.

How has Mepact been studied?

Mepact has been studied in one main study involving 678 patients aged between one and 31 years with high-grade non-metastatic osteosarcoma. After surgery to remove the cancer, all of the patients were given various combinations of anticancer medicines. Half of the patients were also given Mepact. The study compared patients who were given Mepact with those who were not. The main measure of effectiveness was the number of patients who survived without the disease coming back. The patients were followed up for up to 10 years.

What benefit has Mepact shown during the studies?

Mepact, used with other anticancer medicines, increased how long patients survived without their disease coming back: 68% of the patients receiving Mepact (231 out of 338) survived without the disease coming back, compared with 61% of the patients who did not receive it (207 out of 340). The risk of dying was also reduced by 28% in patients receiving Mepact.

What is the risk associated with Mepact?

The most common side effects with Mepact (seen in more than 1 patient in 10) are anaemia (low red blood cell counts), loss of appetite, headache, dizziness, tachycardia (rapid heartbeat), hypertension (high blood pressure), hypotension (low blood pressure), dyspnoea (difficulty breathing), tachypnoea (rapid breathing), cough, vomiting, diarrhoea, constipation, abdominal pain (stomach ache), nausea, hyperhidrosis (excessive sweating), myalgia (muscle pain), arthralgia (joint pain), back pain, pain in extremity (the arms and legs), fever, chills, fatigue (tiredness), hypothermia (low body temperature), general pain, malaise (feeling unwell), asthenia (weakness) and chest pain. For the full list of all side effects reported with Mepact, see the package leaflet.

Mepact should not be used in people who may be hypersensitive (allergic) to mifamurtide or any of the other ingredients. It must not be used at the same time as ciclosporin or other calcineurin inhibitors (medicines that reduce the activity of the immune system), or high doses of non-steroidal anti-inflammatory drugs (NSAIDs; used to treat pain and inflammation).

Why has Mepact been approved?

The CHMP decided that Mepact's benefits are greater than its risks when used with other anticancer medicines and recommended that it be given marketing authorisation.

Other information about Mepact:

The European Commission granted a marketing authorisation valid throughout the European Union for Mepact on 6 March 2009. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for Mepact can be found [here](#). For more information about treatment with Mepact, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Mepact is available [here](#).

This summary was last updated in 09-2013.