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EPAR summary for the public

Kepivance

palifermin

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

What is Kepivance?

Kepivance is a powder that is made up into a solution for injection. It contains the active substance palifermin.

What is Kepivance used for?

Kepivance is used to decrease the frequency, duration and severity of oral mucositis (inflammation of the lining of the mouth, ranging from soreness and redness to severe ulceration). Kepivance is used in adults who are likely to develop severe mucositis because they have blood cancer, and are being treated with myeloablative chemotherapy (medicines to destroy the bone marrow) in combination with radiotherapy (treatment with radiation) and an autologous haematopoietic stem-cell transplant (a transplant of their own blood-producing cells).

The medicine can only be obtained with a prescription.

How is Kepivance used?

The use of Kepivance should be supervised by a doctor who has experience in anticancer therapy.

It is given as an injection into a vein for a total of six doses. Three doses are given on three consecutive days before myeloablative therapy, finishing 24 to 48 hours before the therapy. The remaining three doses are given on three consecutive days after myeloablative therapy, with the first dose given on the day of the stem-cell transplant.

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How does Kepivance work?

The active substance in Kepivance, palifermin, is a growth factor that stimulates the 'epithelial' cells that line the mouth and gastrointestinal tract to grow and develop. Palifermin is very similar to a natural growth factor found in the body called keratinocyte growth factor (KGF).

Epithelial cells in the mouth are normally replaced by the body every few days. In patients receiving chemotherapy and radiotherapy, the cells are not replaced as quickly, which leads to the development of mucositis. Kepivance stimulates the growth of the epithelial cells, helping to reduce the incidence, severity and duration of oral mucositis in cancer patients undergoing intensive therapy.

Palifermin is produced by a method known as 'recombinant DNA technology': it is made by a bacterium that has received a gene (DNA), which makes it able to produce palifermin. The replacement palifermin acts in the same way as naturally produced KGF.

How has Kepivance been studied?

Kepivance has been compared with placebo (a dummy treatment) in one main study in 212 adults receiving chemotherapy and radiotherapy for a blood cancer (mostly non-Hodgkin's lymphoma). The main measure of effectiveness was the number of days during which patients experienced severe oral mucositis.

At the request of the CHMP, the company carried out a further study comparing two schedules of Kepivance with placebo. The study involved 281 adults who were receiving chemotherapy to treat multiple myeloma (a type of blood cancer), but without any radiotherapy.

What benefit has Kepivance shown during the studies?

In the main study, the patients receiving chemotherapy and radiotherapy had severe oral mucositis for a shorter time if they received Kepivance (3.7 days, on average) than if they received placebo (10.4 days, on average). Patients receiving Kepivance also reported less mouth and throat soreness with improved swallowing, drinking, eating and talking. However, in the study of patients receiving chemotherapy without radiation, there was no difference in the severity of mucositis between the patients receiving placebo and those receiving either schedule of Kepivance.

What is the risk associated with Kepivance?

The most common side effects with Kepivance (seen in more than 1 patient in 10) are dysgeusia (taste disturbances), increased levels of lipase and amylase (enzymes used in digestion), hypertrophy (increase in the number or size of cells) or discoloration of the mouth and tongue, rash, pruritus (itching), erythema (redness), arthralgia (joint pain), oedema (swelling), pain and pyrexia (fever). For the full list of all side effects reported with Kepivance, see the package leaflet.

Kepivance should not be used in people who may be hypersensitive (allergic) to palifermin, proteins produced by *Escherichia coli* (a bacterium) or any of the other ingredients.

Why has Kepivance been approved?

The CHMP decided that Kepivance's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Kepivance:

The European Commission granted a marketing authorisation valid throughout the European Union for Kepivance on 25 October 2005.

The full EPAR for Kepivance can be found here. For more information about treatment with Kepivance, read the package leaflet (also part of the EPAR).

This summary was last updated in 03-2016.