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EPAR summary for the public

Zometa

Zoledronic acid

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

What is Zometa?

Zometa is a medicine that contains the active substance zoledronic acid. It is available as a powder (4mg) and solvent, and as a concentrate (4mg/5ml), both of which are made up into a solution for infusion (drip into a vein), and as a pre-prepared solution for infusion (4mg/100ml).

What is Zometa used for?

Zometa can be used to prevent bone complications in adults with advanced cancer that is affecting the bone. This includes fractures (breaks in the bone), spinal compression (when the spinal cord is compressed by the bone), bone disorders needing radiotherapy (treatment with radiation) or surgery, and hypercalcaemia (high levels of calcium in the blood). Zometa can also be used to treat the hypercalcaemia caused by tumours.

The medicine can only be obtained with a prescription.

How is Zometa used?

Zometa must only be used by a doctor who has experience in the use of this type of medicine given into a vein.

The usual dose of Zometa is one infusion of 4 mg over at least 15 minutes. When used to prevent bone complications, the infusion can be repeated every three to four weeks, and patients should also take supplements of calcium and vitamin D. A lower dose is recommended for patients with bone

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metastases (when cancer has spread to the bone) if they have mild to moderate problems with their kidneys. It is not recommended for patients with severe kidney problems.

How does Zometa work?

The active substance in Zometa, zoledronic acid, is a bisphosphonate. It stops the action of the osteoclasts, the cells in the body that are involved in breaking down the bone tissue. This leads to less bone loss. The reduction of bone loss helps to make bones less likely to break, which is useful in preventing fractures in cancer patients with bone metastases.

Patients with tumours can have high levels of calcium in their blood, released from the bones. By preventing the breakdown of bones, Zometa also helps to reduce the amount of calcium released into the blood.

How has Zometa been studied?

Zometa has been studied in over 3,000 adults with bone metastases in three main studies looking at its ability to prevent bone damage. Zometa was compared with placebo (a dummy treatment) in two of the studies, and with pamidronate (another bisphosphonate) in the third. The main measure of effectiveness was the number of patients who developed at least one new 'skeletal event' over 13 months. This included any bone complications needing treatment with radiotherapy or surgery, any fractures or any spinal compression.

Zometa has also been compared with pamidronate in two main studies involving a total of 287 adults with hypercalcaemia caused by tumours. The main measure of effectiveness was the number of patients whose calcium levels had returned to normal within 10 days after treatment.

What benefit has Zometa shown during the studies?

In the first two studies of patients with bone metastases, the number of patients who developed a new skeletal event was lower with Zometa (33 to 38%) than with placebo (44%). In the third study, Zometa was as effective as pamidronate: 44% of the patients receiving Zometa had at least one skeletal event, compared with 46% of those receiving pamidronate.

In patients with hypercalcaemia, Zometa was more effective than pamidronate. Looking at the results of the two studies together, 88% of the patients receiving Zometa had normal calcium levels within 10 days after treatment, compared with 70% of those receiving pamidronate.

What is the risk associated with Zometa?

The most common side effect with Zometa (seen in more than 1 patient in 10) is hypophosphataemia (low blood phosphate levels). Osteonecrosis of the jaw (damage to the bones of the jaw, which could lead to pain, sores in the mouth or loosening of teeth) has been reported uncommonly (seen in between 1 and 10 patients in 1,000). For the full list of all side effects reported with Zometa, see the package leaflet.

Zometa must not be used in people who are hypersensitive (allergic) to zoledronic acid, other bisphosphonates or any of the other ingredients. Zometa should not be used in pregnant or breast-feeding women.

Why has Zometa been approved?

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

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

A risk management plan has been developed to ensure that Zometa 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 Zometa, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Zometa will provide a card to inform patients about the risk of osteonecrosis of the jaw and to instruct them to contact their doctor if they experience symptoms.

Other information about Zometa

The European Commission granted a marketing authorisation valid throughout the European Union for Zometa on 20 March 2001.

The full EPAR for Zometa 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 Zometa, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2015.