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EPAR summary for the public

Zoledronic acid Actavis

zoledronic acid

This is a summary of the European public assessment report (EPAR) for Zoledronic acid Actavis. 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 Zoledronic acid Actavis.

What is Zoledronic acid Actavis?

Zoledronic acid Actavis is a medicine that contains the active substance zoledronic acid (4 mg). It is available as a concentrate to be made into a solution for infusion (drip) into a vein.

Zoledronic acid Actavis is a 'generic medicine'. This means that Zoledronic acid Actavis is similar to a 'reference medicine' already authorised in the European Union (EU) called Zometa. For more information on generic medicines, see the question-and-answer document here.

What is Zoledronic acid Actavis used for?

Zoledronic acid Actavis 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). Zoledronic acid Actavis can also be used to treat the hypercalcaemia caused by tumours.

The medicine can only be obtained with a prescription.

How is Zoledronic acid Actavis used?

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

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The usual dose of Zoledronic acid Actavis 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 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 Zoledronic acid Actavis work?

The active substance in Zoledronic acid Actavis, 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, Zoledronic acid Actavis also helps to reduce the amount of calcium released into the blood.

How has Zoledronic acid Actavis been studied?

The company provided data from the published literature on zoledronic acid. No additional studies were needed as Zoledronic acid Actavis is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Zometa.

What are the benefits and risks of Zoledronic acid Actavis?

Because Zoledronic acid Actavis is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why has Zoledronic acid Actavis been approved?

The CHMP concluded that, in accordance with EU requirements, Zoledronic acid Actavis has been shown to be comparable to Zometa. Therefore, the CHMP's view was that, as for Zometa, the benefit outweighs the identified risk. The Committee recommended that Zoledronic acid Actavis be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Zoledronic acid Actavis?

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

In addition, the company that markets Zoledronic acid Actavis will provide a card to inform patients about the risk of osteonecrosis of the jaw (damage to the bones of the jaw, which could lead to pain, sores in the mouth or loosening of teeth) and to instruct them to contact their doctor if they experience symptoms.

Other information about Zoledronic acid Actavis

The European Commission granted a marketing authorisation valid throughout the European Union for Zoledronic acid Actavis on 20 April 2012.

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

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 02-2016.