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EPAR summary for the public

Zoledronic Acid Hospira

zoledronic acid

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

What is Zoledronic Acid Hospira?

Zoledronic Acid Hospira is a medicine that contains the active substance zoledronic acid. It is available as a concentrate (4 mg/5 ml) to be made up into a solution for infusion (drip) into a vein, and as solutions for infusion (4 mg/100 ml and 5 mg/100 ml).

Zoledronic Acid Hospira is a 'generic' and a 'hybrid' medicine. This means that it is similar to one or more 'reference medicines' already authorised in the European Union (EU). The reference medicine for the 4 mg/5 ml concentrate and 4 mg/100 ml solution is Zometa. Aclasta is the reference medicine for the 5 mg/100 ml solution.

For more information on generic and hybrid medicines, see the question-and-answer document here.

What is Zoledronic Acid Hospira used for?

Zoledronic Acid Hospira 4 mg/5 ml concentrate and 4 mg/100 ml solution are 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). They can also be used to treat the hypercalcaemia caused by tumours.

Zoledronic Acid Hospira 5 mg/100 ml solution is used to treat Paget's disease of the bone in adults. This is a long-term disease where the normal process of bone growth is altered, which causes bones to become weakened or deformed.

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The medicine can only be obtained with a prescription.

How is Zoledronic Acid Hospira used?

For the prevention of bone complications and treatment of hypercalcaemia caused by tumours, the usual dose of Zoledronic Acid Hospira 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.

For the treatment of Paget's disease of the bone, Zoledronic Acid Hospira is given as one infusion lasting at least 15 minutes. An additional infusion, given at least one year after the first one, can be considered if the patient's disease comes back. Patients must have adequate fluids before and after treatment, and should receive adequate supplements of vitamin D and calcium. See the package leaflet for full details.

How does Zoledronic Acid Hospira work?

The active substance in Zoledronic Acid Hospira, 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 disease activity in Paget's disease. 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 Hospira also helps to reduce the amount of calcium released into the blood.

How has Zoledronic Acid Hospira been studied?

The company provided data from the published literature on zoledronic acid. No additional studies were needed as Zoledronic Acid Hospira is given by infusion and contains the same active substance as the reference medicines, Zometa and Aclasta.

What are the benefits and risks of Zoledronic Acid Hospira?

Because Zoledronic Acid Hospira is given by infusion and contains the same active substance as the reference medicines, its benefits and risks are taken as being the same as the reference medicines'.

Why has Zoledronic Acid Hospira been approved?

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

What measures are being taken to ensure the safe and effective use of Zoledronic Acid Hospira?

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

Other information about Zoledronic Acid Hospira

The European Commission granted a marketing authorisation valid throughout the European Union for Zoledronic Acid Hospira on 19 November 2012.

The full EPAR for Zoledronic Acid Hospira 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 Hospira, 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 04-2014.