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Zoledronic Acid Accord (*zoledronic acid*)

An overview of Zoledronic Acid Accord and why it is authorised in the EU

What is Zoledronic Acid Accord and what is it used for?

Zoledronic Acid Accord is a medicine 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 Accord can also be used to treat hypercalcaemia caused by tumours.

Zoledronic Acid Accord contains the active substance zoledronic acid and is a 'generic medicine'. This means that Zoledronic Acid Accord contains the same active substance and works in the same way as 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.

How is Zoledronic Acid Accord used?

Zoledronic Acid Accord can only be obtained with a prescription and must only be prescribed and given by a healthcare professional who has experience in the use of this type of medicine given into a vein.

The medicine is given as an infusion (drip) into a vein. The usual dose 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 moderately reduced kidney function. It is not recommended for patients with severely reduced kidney function.

For more information about using Zoledronic Acid Accord, see the package leaflet or contact your doctor or pharmacist.

How does Zoledronic Acid Accord work?

The active substance in Zoledronic Acid Accord, 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 reduces 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.

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

How has Zoledronic Acid Accord been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Zometa, and do not need to be repeated for Zoledronic Acid Accord.

As for every medicine, the company provided studies on the quality of Zoledronic Acid Accord. There was no need for 'bioequivalence' studies to investigate whether Zoledronic Acid Accord is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Zoledronic Acid Accord is given by infusion into a vein, so the active substance is delivered straight into the bloodstream.

What are the benefits and risks of Zoledronic Acid Accord?

Because Zoledronic Acid Accord is a generic medicine, its benefits and risks are taken as being the same as the reference medicines'.

Why is Zoledronic Acid Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Zoledronic Acid Accord has been shown to have comparable quality and to be comparable to Zometa. Therefore, the Agency's view was that, as for Zometa, the benefit outweighs the identified risk and it can be authorised for use in the EU.

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

The company that markets Zoledronic Acid Accord will provide a card to inform patients receiving Zoledronic Acid Accord about the risk of osteonecrosis of the jaw and to instruct them to contact their doctor if they get symptoms. Osteonecrosis of the jaw is a condition affecting the bones of the jaw, which could lead to pain, sores in the mouth or loose teeth.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Zoledronic Acid Accord have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Zoledronic Acid Accord are continuously monitored. Side effects reported with Zoledronic Acid Accord are carefully evaluated and any necessary action taken to protect patients.

Other information about Zoledronic Acid Accord

Zoledronic Acid Accord received a marketing authorisation valid throughout the EU on 16 January 2014.

Further information on Zoledronic Acid Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/zoledronic-acid-accord. Information on the reference medicine can also be found on the Agency's website.

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