



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/467454/2012  
EMA/H/C/002482

## EPAR summary for the public

---

# Zoledronic acid Mylan

zoledronic acid

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

## What is Zoledronic acid Mylan?

Zoledronic acid Mylan is a medicine that contains the active substance zoledronic acid. It is available as a 4mg/5ml concentrate for a solution for infusion.

Zoledronic acid Mylan is a 'generic medicine'. This means that Zoledronic acid Mylan 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 Mylan used for?

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

The medicine can only be obtained with a prescription.

## How is Zoledronic acid Mylan used?

Zoledronic acid Mylan 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 Zoledronic acid Mylan 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 Mylan work?**

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

### **How has Zoledronic acid Mylan been studied?**

The company provided data from the published literature on zoledronic acid. No additional studies in patients were needed as Zoledronic acid Mylan 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 Mylan?**

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

### **Why has Zoledronic acid Mylan been approved?**

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

### **Other information about Zoledronic acid Mylan**

The European Commission granted a marketing authorisation valid throughout the European Union for Zoledronic acid Mylan on 23 August 2012.

The full EPAR for Zoledronic acid Mylan can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports). For more information about treatment with Zoledronic acid Mylan, 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 August 2012.