LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Zoledronic acid Oresund Pharma
zoledronic acid (anhydrous), zoledronic acid monohydrate

SE/H/2273/01-02

This module reflects the scientific discussion for the approval of Zoledronic acid Oresund Pharma. The Summary Public Assessment Report was written in June 2018 by the previous RMS (PT) after initial procedure PT/H/1405/01-02. RMS transfer from PT to SE was completed 2022-05-17.

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infarmed
Autoridade Nacional do Medicamento
e Produtos de Saúde I.P.

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Date: 07-06-2018

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Solution for infusion, 4 mg/100 ml, 5 mg/100 ml

This is a summary of the public assessment report (PAR) for Zoledronic acid Oresund Pharma. It explains how Zoledronic acid Oresund Pharma was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Zoledronic acid Oresund Pharma.

For practical information about using Zoledronic acid Oresund Pharma, patients should read the package leaflet or contact their doctor or pharmacist.

What is Ácido Zoledrónico Amneal and what is it used for?

Ácido Zoledrónico Amneal 4 mg/100 ml and 5 mg/100 ml Solution for Infusion is a 'generic medicine'. This means that Ácido Zoledrónico Amneal 4 mg/100 ml and 5 mg/100 ml Solution for Infusion is similar to a 'reference medicine' already authorised in the European Union (EU) called Zometa 4 mg powder and solvent for solution for infusion.

The active substance in Ácido Zoledrónico Amneal 4 mg/100 ml Solution for Infusion, which belongs to a group of substances called bisphosphonates. Zoledronic acid works by attaching itself to the bone and slowing down the rate of bone change. It is used:

- **To prevent bone complications,** e.g. fractures, in adult patients with bone metastases (spread of cancer from primary site to the bone).
- **To reduce the amount of calcium** in the blood in adult patients where it is too high due to the presence of a tumour. Tumours can accelerate normal bone change in such a way that the release of calcium from bone is increased. This condition is known as tumour-induced hypercalcaemia (TIH).

Ácido Zoledrónico Amneal 5 mg/100 ml Solution for Infusion contains the active substance zoledronic acid. It belongs to a group of medicines called bisphosphonates and is used to treat post-menopausal women and adult men with osteoporosis or osteoporosis caused by treatment with steroids, and Paget's disease of the bone in adults.

How does Ácido Zoledrónico Amneal work?

Pharmacotherapeutic group: Drugs for treatment of bone diseases, bisphosphonates

Zoledronic acid belongs to the class of bisphosphonates and acts primarily on bone. It is an inhibitor of osteoclastic bone resorption.

How is Ácido Zoledrónico Amneal used?

The pharmaceutical form of Ácido Zoledrónico Amneal is Solution for Infusion and the route of administration is intravenous use..

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Ácido Zoledrónico Amneal have been shown in studies?

No additional studies were needed as Ácido Zoledrónico Amneal is a generic medicine that is given by <infusion/intravenous injection and contains the same active substance as the reference medicine, <reference medicine called Zometa.

What are the possible side effects of Ácido Zoledrónico Amneal?

Because Ácido Zoledrónico Amneal is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of restrictions, see the package leaflet.

Why is Ácido Zoledrónico Amneal approved?

It was concluded that, in accordance with EU requirements, Ácido Zoledrónico Amneal 4 mg/100 ml and 5 mg/100 ml Solution for Infusion has been shown to have comparable quality and to be bioequivalent/be comparable to Zometa 4 mg powder and solvent for solution for infusion. Therefore, the INFARMED, I.P. decided that, as for <reference medicine called Zometa 4 mg powder and solvent for solution for infusion, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Ácido Zoledrónico Amneal?

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

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Ácido Zoledrónico Amneal

The marketing authorisation for Ácido Zoledrónico Amneal 4 mg/100 ml and 5 mg/100 ml Solution for Infusion was granted on 07-06-2018

The full PAR for Ácido Zoledrónico Amneal 4 mg/100 ml and 5 mg/100 ml Solution for Infusion can be found on the website http://www.infarmed.pt/infomed/inicio.php. For more information about treatment with Ácido Zoledrónico Amneal, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in MM-YYYY.