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EPAR summary for the public

Zoledronic acid Teva Pharma

zoledronic acid

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

What is Zoledronic acid Teva Pharma?

Zoledronic acid Teva Pharma is a solution for infusion (drip) into a vein that contains the active substance zoledronic acid (5 mg).

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

What is Zoledronic acid Teva Pharma used for?

Zoledronic acid Teva Pharma is used to treat osteoporosis (a disease that makes bones fragile) in women who have been through the menopause and in men. It is used in patients who are at risk of fractures (broken bones), including those who have recently broken their hip in a minor trauma such as a fall, and in patients whose osteoporosis is linked to long-term treatment with glucocorticoids (a type of steroid).

Zoledronic acid Teva Pharma is also used to treat Paget's disease of the bone in adults. This is a disease where the normal process of bone growth is changed.

The medicine can only be obtained with a prescription.

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How is Zoledronic acid Teva Pharma used?

Zoledronic acid Teva Pharma is given as an infusion lasting at least 15 minutes. This can be repeated once a year in patients being treated for osteoporosis. Patients who have broken their hip should not receive Zoledronic acid Teva Pharma any earlier than two weeks after the operation to repair the fracture.

For Paget's disease, only one infusion of Zoledronic acid Teva Pharma is usually given, but additional infusions can be considered if the patient's disease comes back. The effect of each infusion lasts for a year or more.

Patients must have adequate fluids before and after treatment, and should receive adequate supplements of vitamin D and calcium. Using paracetamol or ibuprofen (anti-inflammatory medicines) shortly after Zoledronic acid Teva Pharma can reduce symptoms such as fever, muscle pain, influenza (flu)-like symptoms, joint pain and headache in the three days following the infusion. In the treatment of Paget's disease of the bone, Zoledronic acid Teva Pharma must only be used by a doctor who has experience in the treatment of the disease. Zoledronic acid Teva Pharma should not be used in patients with severe kidney problems. See the package leaflet for full details.

How does Zoledronic acid Teva Pharma work?

Osteoporosis happens when not enough new bone grows to replace the bone that is naturally broken down. Gradually, the bones become thin and fragile, and more likely to fracture. In women, osteoporosis is more common after the menopause, when the levels of the female hormone oestrogen fall. Osteoporosis can also occur in both sexes as a side effect of glucocorticoid treatment. In Paget's disease, the bone breaks down more quickly, and when it grows back, it is weaker than normal.

The active substance in Zoledronic acid Teva Pharma, 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 in osteoporosis and less disease activity in Paget's disease.

How has Zoledronic acid Teva Pharma been studied?

No additional studies were needed as Zoledronic acid Teva Pharma is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Aclasta.

What are the benefits and risks of Zoledronic acid Teva Pharma?

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

Why has Zoledronic acid Teva Pharma been approved?

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

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

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

Other information about Zoledronic acid Teva Pharma

The European Commission granted a marketing authorisation valid throughout the European Union for Zoledronic acid Teva Pharma on 16 August 2012.

The full EPAR for Zoledronic acid Teva Pharma 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 Teva Pharma, 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 04-2015.