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EPAR summary for the public

Zoledronic acid Teva Generics

zoledronic acid

Medicinal product no longer authorised

This is a summary of the European public assessment report (EPAR) for Zoledronic acid Teva Generics. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Zoledronic acid Teva Generics.

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

What is Zoledronic acid Teva Generics and what is it used for?

Zoledronic acid Teva Generics is a medicine that contains zoledronic acid (5mg). It 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) and in patients whose osteoporosis is linked to long-term treatment with glucocorticoids (a type of steroid).

Zoledronic acid Teva Generics 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 altered.

Zoledronic acid Teva Generics is a 'generic medicine'. This means that Zoledronic acid Teva Generics 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.

How is Zoledronic acid Teva Generics used?

Zoledronic acid Teva Generics is available as a solution for infusion (drip) into a vein; the medicine can only be obtained with a prescription.

Zoledronic acid Teva Generics is given as an infusion lasting at least 15 minutes. This can be repeated once a year in patients being treated for osteoporosis. For Paget's disease, only one infusion of

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Zoledronic acid Teva Generics 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. In the treatment of Paget's disease, Zoledronic acid Teva Generics must only be used by a doctor who has experience in the treatment of the disease. See the package leaflet for full details.

How does Zoledronic acid Teva Generics 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 Generics, 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 Generics been studied?

No additional studies were needed as Zoledronic acid Teva Generics 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 Generics?

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

Why is Zoledronic acid Teva Generics approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Zoledronic acid Teva Generics 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 Generics be approved for use in the EU.

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

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

Further information can be found in the summary of the risk management plan.

Other information about Zoledronic acid Teva Generics

The European Commission granted a marketing authorisation valid throughout the European Union for Zoledronic acid Teva Generics on 27 March 2014.

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The full EPAR and risk management plan summary for Zoledronic acid Teva Generics 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 Generics, 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 03-2014.

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