1. What Zoledronic acid is and what it is used for

Zoledronic acid contains the active substance zoledronic acid, which 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 corticosteroids used to treat inflammation, and Paget’s disease of the bone in adults.

Osteoporosis

Osteoporosis is a disease that involves the thinning and weakening of the bones and is common in women after the menopause, but can also occur in men. At the menopause, a hormone known as estrogen, which helps to keep bones healthy. Following the menopause bone loss occurs, bones become weaker and break more easily. Osteoporosis could also occur in men and women because of the long term use of steroids, which can affect the strength of bones. Many patients with osteoporosis have no symptoms but they are at risk of breaking bones because osteoporosis has made their bones weaker. Decreased circulating levels of sex hormones, mainly oestrogens converted from androgens, also play a role in the more gradual bone loss observed in men. In both women and men, Zoledronic acid strengthens the bone and therefore makes it less likely to break. Zoledronic acid is also less likely to cause fractures (including those of the spine) in women who have had sections of their intestine removed.

Paget’s disease of the bone

It is normal that old bone is removed and is replaced with new bone material. This process is called remodelling. In Paget’s disease, bone remodelling is too rapid and new bone is formed in a disorganised fashion, which makes it weaker than normal. If the disease is not treated, bones may become deformed and painful, and may break. Zoledronic acid works by returning the bone remodelling process to normal, securing normal function of normal bone, thus restoring strength to the bone.

What is in this leaflet:

1. What Zoledronic acid is and what it is used for
2. What you need to know before you are given Zoledronic acid
3. How Zoledronic acid is given
4. How to store Zoledronic acid
5. What to do if you think you have taken too much Zoledronic acid
6. What happens if you stop taking Zoledronic acid
7. Side effects
8. Before receiving Zoledronic acid treatment, tell your doctor, pharmacist or nurse if:
   • you have any problems with your mouth or teeth such as poor dental health, gum disease, or a planned tooth extraction;
   • you do not receive routine dental care or have not had a dental check-up for a long time;
   • you are a smoker (as this may increase the risk of dental problems).
9. If you have hypocalcaemia, you should maintain good oral hygiene (including regular tooth brushing) and receive routine dental check-ups. If you wear dentures, inform your doctor about your dental treatment or are due to undergo dental surgery (e.g. tooth extractions), inform your doctor about your dental treatment, and tell your dentist that you are being treated with Zoledronic acid. Contact your doctor and dentist immediately if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, or non-healing of sores or discharge, as these could be signs of osteonecrosis of the jaw.
10. Monitoring test

Your doctor should do a blood test to check your kidney function (levels of creatinine) before each dose of Zoledronic acid. It is important for you to drink at least 2 glasses of fluid (such as water), within a few hours before receiving Zoledronic acid. It is important for you to drink at least 2 glasses of fluid (such as water), within a few hours before receiving Zoledronic acid.

2. What you need to know before you are given Zoledronic acid

Beverley

Your doctor will let you know when to return for your next appointment and discuss this with your doctor or pharmacist if you have any questions or concerns about Zoledronic acid.

Be aware:

1. If you have had sections of your intestine removed.
2. If you have had some or all of the parathyroid glands in:
   • • if you have had sections of your intestine removed.
   • • if you have had some or all of the parathyroid glands in:

3. How Zoledronic acid is given

Follow all instructions given to you by your doctor, pharmacist or nurse carefully before you are given Zoledronic acid.

You must not be given Zoledronic acid:

• if you are allergic to Zoledronic acid, other bisphosphonates or any of the other ingredients of this medicine (listed in section 6).
• if you have hypercalcemia (this means that the levels of calcium in your blood are too high).
• if you have severe kidney problems.
• if you are pregnant.
• if you are breast-feeding.

Matters to take into account:

Talk to your doctor before you are given Zoledronic acid.

• if you are being treated with any medicines containing zoledronic acid, which is also the active substance of Zoledronic acid and is used in adult patients with certain types of cancer to prevent bone complications or to reduce the amount of calcium.
• if you have a kidney problem, or used to have one.
• if you are unable to take daily calcium supplements.
• if you have had some or all of the parathyroid glands in.
• if you have had sections of your intestine removed.

A side effect called osteonecrosis of the jaw (ONJ) (bone damage in the jaw) has been reported in the joint-marketing selling in patients receiving zoledronic acid for osteoporosis. ONJ can also occur after stopping treatment. It is important to try to prevent ONJ developing as it is a painful condition that can be difficult to treat. In order to reduce the risk of developing osteonecrosis of the jaw, there are some measures you should take:

Before receiving Zoledronic acid treatment, tell your doctor, pharmacist or nurse if:

• you have any problems with your mouth or teeth such as poor dental health, gum disease, or a planned tooth extraction;
• you do not receive routine dental care or have not had a dental check-up for a long time;
• you are a smoker (as this may increase the risk of dental problems).

If you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, or non-healing of sores or discharge, as these could be signs of osteonecrosis of the jaw (ONJ), contact your doctor immediately.

3. How Zoledronic acid is given

For single use only. Any unused solution should be disposed of as hazardous waste.

Aseptic techniques must be followed during preparation of Zoledronic acid.

For each infusion:

• The unopened bottle does not require any special storage conditions.
• Store at 2°C – 8°C. Allow the refrigerated solution to reach room temperature before use.
• This medicinal product contains less than 1 mmol sodium (as monohydrate) corresponding to 0.05mg sodium.

4. Side effects

The other ingredients are mannitol, sodium citrate and sodium hydroxide.

Common (may affect more than 1 in 10 people)

• Swelling, redness, pain and itching to the eyes or eye irritation.

Uncommon (may affect up to 1 in 100 people)

• Belching.

Very rare (may affect less than 1 in 1000 people)

• Breathing difficulties.

Rare (may affect up to 1 in 1000 people)

• Confusion.
• Possibility of hearing damage.

Very rare (may affect less than 1 in 10 000 people)

• Swelling, redness, pain and itching to the skin.
• Numbness, extreme tiredness, trembling, temporary loss of smell.

Very rare (may affect less than 1 in 100 000 people)

• Breathing difficulties.

Reporting of side effects

If you have any further questions on the use of this medicine, please go to your next appointment and discuss this with your doctor or pharmacist.

What happens if you stop taking Zoledronic acid

If you stop taking Zoledronic acid, you may be at risk of developing osteoporosis (a disease that affects the bone and makes it weaker). Osteoporosis may be caused by a lack of calcium (mineral) and vitamin D in the diet or from lack of sunlight. If you stop taking Zoledronic acid, you may be at risk of developing osteoporosis (a disease that affects the bone and makes it weaker). Osteoporosis may be caused by a lack of calcium (mineral) and vitamin D in the diet or from lack of sunlight.
Paget’s disease
For the treatment of Paget’s disease, Zoledronic acid should be prescribed only by physicians with experience in the treatment of Paget’s disease of the bone.

The usual dose is 5 mg, given to you as one initial infusion into a vein by your doctor or nurse. The infusion will take at least 15 minutes. Zoledronic acid may work for longer than one treatment.

If you are not sure if you need to be treated, you should discuss this with your doctor.

Your doctor may advise you to take calcium and vitamin D supplements (e.g. tablets) for at least the first ten days after being given Zoledronic acid. It is important that you follow this advice carefully so that the level of calcium in your blood does not become too low in the period after the infusion. Your doctor will inform you regarding the symptoms associated with hypocalcaemia.

Zoledronic acid with food and drink
Make sure you drink enough fluids (at least one or two glasses before and after the treatment with Zoledronic acid)

Dental care. You may wish to consult your dentist before you are given Zoledronic acid. This is especially important in patients who have dentures (water pills) and in elderly patients. If you have had sections of your intestine removed.

if you have a kidney problem, or used to have one.

if you are being treated with any medicine containing calcium.

Talk to your doctor before you are given Zoledronic acid:

• if you are pregnant.

• if you are allergic to zoledronic acid, other medicines containing zoledronic acid, or any other medicines containing zoledronic acid (anhydrous).

• if you are allergic to any other medicines containing bisphosphonates.

• if you have previously been treated with a bisphosphonate.

• if you have a history of breathing difficulties after starting treatment with bisphosphonates.

• if you have previously had an injection of pamidronate, and are due to have another injection of pamidronate.

• if you have had parts of your jaw surgically removed.

In patients with Paget's disease, symptoms due to low blood calcium, such as muscle cramps, or numbness, or a tingling sensation especially in the areas around the mouth have been reported.

• if you are being treated with any medicine containing inorganic phosphates.

Before stopping Zoledronic acid therapy
If you are considering stopping Zoledronic acid treatment, please go to your next appointment and discuss this with your doctor. Your doctor will let you know when to return for your next appointment.

You should be treated with Zoledronic acid for at least 15 months.

If you have any further questions about the use of this medicine, talk to your doctor, pharmacist or nurse.

Before you receive Zoledronic acid

• if you are allergic to zoledronic acid (anhydrous), other medicines containing zoledronic acid, or any other medicines containing bisphosphonates.

• if you have a kidney problem, or used to have one.

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