

**Package leaflet: Information for the patient**  
**Zoledronic Acid 5mg/100ml Solution for Infusion**  
(Referred to as Zoledronic Acid Infusion in the remainder of this leaflet)

**Read all of this leaflet carefully before you are given this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Zoledronic Acid Infusion is and what it is used for
2. What you need to know before you are given Zoledronic Acid Infusion
3. How Zoledronic Acid Infusion is given
4. Possible side effects
5. How to store Zoledronic Acid Infusion
6. Contents of the pack and other information

**1. What Zoledronic Acid Infusion is and what it is used for**

Zoledronic Acid Infusion contains the active substance zoledronic acid. It belongs to a group of medicines called bisphosphonates and is used to treat Paget's disease of the bone in adults.

**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 disordered fashion, which makes it weaker than normal. If the disease is not treated, bones may become deformed and painful, and may break. Zoledronic Acid Infusion works by returning the bone remodelling process to normal, securing formation of normal bone, thus restoring strength to the bone.

**2. What you need to know before you are given Zoledronic Acid Infusion**

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

**You must not be given Zoledronic Acid Infusion:**

- 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 hypocalcaemia (this means that the levels of calcium in your blood are too low).
- if you have severe kidney problems.
- if you are pregnant.
- if you are breast-feeding.

**Warnings and precautions**

Talk to your doctor before you are given Zoledronic Acid Infusion:

- if you are being treated with any medicine containing zoledronic acid, which is also the active substance of Zoledronic Acid Infusion (zoledronic acid 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 your neck surgically removed.
- 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 post-marketing setting in patients receiving Zoledronic Acid Infusion for osteoporosis. ONJ can also occur after stopping treatment.

It is important to try and 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 precautions you should take.

Before receiving Zoledronic Acid Infusion, 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);
- you have previously been treated with a bisphosphonate (used to treat or prevent bone disorders);
- you are taking medicines called corticosteroids (such as prednisolone or dexamethasone)
- you have cancer.

Your doctor may ask you to undergo a dental examination before you start treatment with Zoledronic Acid Infusion.

While being treated with Zoledronic Acid Infusion, you should maintain good oral hygiene (including regular teeth brushing) and receive routine dental check-ups. If you wear dentures you should make sure these fit properly. If you are under 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 Infusion. 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.

#### **Monitoring test**

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

#### **Children and adolescents**

Zoledronic Acid Infusion is not recommended for anyone under 18 years of age. The use of Zoledronic Acid Infusion in children and adolescents has not been studied.

#### **Other medicines and Zoledronic Acid Infusion**

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

It is important for your doctor to know all the medicines you are taking, especially if you are taking any medicines known to be harmful to your kidneys (e.g. aminoglycosides) or diuretics ("water pills") that may cause dehydration.

#### **Pregnancy and breast-feeding**

You must not be given Zoledronic Acid Infusion if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

Ask your doctor, pharmacist or nurse for advice before taking this medicine.

#### **Driving and using machines**

If you feel dizzy while taking Zoledronic Acid Infusion, do not drive or use machines until you feel better.

#### **Zoledronic Acid Infusion contains sodium**

This medicinal product contains less than 1 mmol sodium (23mg) per dose, i.e. essentially 'sodium-free'.

### **3. How Zoledronic Acid Infusion is given**

Follow carefully all instructions given to you by your doctor or nurse. Check with your doctor or nurse if you are not sure.

#### **Paget's disease**

For the treatment of Paget's disease, Zoledronic Acid Infusion 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 Infusion may work for longer than one year, and your doctor will let you know if you need to be treated again.

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 Infusion. 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 Infusion with food and drink**

Make sure you drink enough fluids (at least one or two glasses) before and after the treatment with Zoledronic Acid Infusion, as directed by your doctor. This will help to prevent dehydration. You may eat normally on the day you are treated with Zoledronic Acid Infusion. This is especially important in patients who take diuretics ("water pills") and in elderly patients (age 65 years or over).

**If you missed a dose of Zoledronic Acid Infusion**

Contact your doctor or hospital as soon as possible to re-schedule your appointment.

**Before stopping Zoledronic Acid Infusion therapy**

If you are considering stopping Zoledronic Acid Infusion treatment, please go to your next appointment and discuss this with your doctor. Your doctor will advise you and decide how long you should be treated with Zoledronic Acid Infusion.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects related to the first infusion are very common (occurring in more than 30% of patients) but are less common following subsequent infusions. The majority of the side effects, such as fever and chills, pain in the muscles or joints, and headache, occur within the first three days following the dose of Zoledronic Acid Infusion. The symptoms are usually mild to moderate and go away within three days. Your doctor can recommend a mild pain reliever such as ibuprofen or paracetamol to reduce these side effects. The chance of experiencing these side effects decreases with subsequent doses of Zoledronic Acid Infusion.

**Some side effects could be serious**Common (may affect up to 1 in 10 people):

- Irregular heart rhythm (atrial fibrillation). It is currently unclear whether Zoledronic Acid Infusion causes this irregular heart rhythm but you should report it to your doctor if you experience such symptoms after you have received Zoledronic Acid Infusion.
- Increased protein (c-reactive protein) in blood

Uncommon (may affect up to 1 in 100 people):

- Swelling, redness, pain and itching to the eyes or eye sensitivity to light.
- Palpitations (feeling your heart is beating too hard or too fast)
- Acute phase reaction with symptoms including bone pain, fever, fatigue, arthralgia, myalgia, rigors and arthritis with subsequent joint swelling

Very rare (may affect up to 1 in 10,000 people):

- Talk to your doctor if you have ear pain, discharge from the ear and/or an ear infection. These could be signs of bone damage in the ear.

Not known (frequency cannot be estimated from the available data)

- Pain in the mouth and/or jaw, swelling or non-healing sores in the mouth or jaw, discharge, numbness or a feeling of heaviness in the jaw, or loosening of a tooth; these could be signs of bone damage in the jaw (osteonecrosis). Tell your doctor and dentist immediately if you experience such symptoms while being treated with Zoledronic Acid Infusion or after stopping treatment.
- Kidney disorders (e.g. decreased urine output) may occur. Your doctor should do a blood test to check your kidney function before each dose of Zoledronic Acid Infusion. It is important for you to drink at least 2 glasses of fluid (such as water), within a few hours before receiving Zoledronic Acid Infusion, as directed by your healthcare provider.

If you experience any of the above side effects, you should contact your doctor immediately.

**Zoledronic Acid Infusion may also cause other side effects**Very common (may affect more than 1 in 10 people)

Fever

Common (may affect up to 1 in 10 people):

Headache, dizziness, sickness, vomiting, diarrhoea, pain in the muscles, pain in the bones and/or joints, pain in the back, arms or legs, flu-like symptoms (e.g. tiredness, chills, joint and muscle pain), chills, feeling of tiredness and lack of interest, weakness, pain, feeling unwell, swelling and/or pain at the infusion site, eye redness.

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

Uncommon (may affect up to 1 in 100 people):

Flu, upper respiratory tract infections, decreased red cell count, loss of appetite, sleeplessness, sleepiness which may include reduced alertness and awareness, tingling sensation or numbness, extreme tiredness, trembling, temporary loss of consciousness, eye infection or irritation or inflammation with pain and redness, spinning sensation, increased blood pressure, flushing, cough, shortness of breath, upset stomach, abdominal pain, constipation, dry mouth, heartburn, skin rash, excessive sweating, itching, skin reddening, neck pain, stiffness in muscles, bones and/or joints, joint swelling, muscle spasms, pain in your chest muscles and rib cage, joint inflammation, muscular weakness, abnormal kidney test results, abnormal frequent urination, swelling of hands, ankles or feet, thirst, toothache, taste disturbances.

**Rare (may affect up to 1 in 1,000 people):**

Unusual fracture of the thigh bone may occur rarely. Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin as this may be an early indication of a possible fracture of the thigh bone. Low levels of phosphate in the blood.  
Eye inflammation, episclera inflammation, iris inflammation.

**Not known (frequency cannot be estimated from the available data)**

Severe allergic reactions including dizziness and difficulty breathing, swelling mainly of the face and throat, decreased blood pressure, dehydration secondary to acute phase reactions (post-dose symptoms such as fever, vomiting and diarrhoea, inflammation of the white part of the eye (sclera) and inflammation of the orbit).

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting systems listed below:

United Kingdom:

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

Malta:

ADR Reporting

Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Zoledronic Acid Infusion**

Your doctor or nurse knows how to store Zoledronic Acid Infusion properly.

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.
- The unopened bottle does not require any special storage conditions.

**6. Contents of the pack and other information**

**What Zoledronic Acid Infusion contains**

- The active substance is zoledronic acid. Each bottle with 100 ml of solution contains 5 mg zoledronic acid anhydrous (as monohydrate). One ml solution contains 0.05 mg zoledronic acid (as monohydrate).
- The other ingredients are mannitol (E421), sodium citrate and water for injections.

**What Zoledronic Acid Infusion looks like and contents of the pack**

Zoledronic Acid Infusion is a clear, colourless solution. It comes in 100 ml plastic bottles as a ready-to-use solution for infusion. It is supplied in packs containing one bottle.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder**

SNIGD (UK Limited), Office Gold, Building 3 Chiswick Park, 566 Chiswick High Road, London, England, W4 5YA.

**Manufacturer**

CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

**Other formats:**

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only). Please be ready to give the following information:

Product name	UK Reference number
Zoledronic Acid 5mg/100ml Solution for Infusion	PL 55539/0047

This is a service provided by the Royal National Institute of Blind People.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

UK: Zoledronic Acid 5mg/100ml Solution for Infusion

Malta: Zoledronic Acid 5mg/100ml Solution for Infusion

**This leaflet was last revised in 10/2021**

## INFORMATION FOR HEALTHCARE PROFESSIONALS

### **Zoledronic Acid 5mg/100ml Solution for Infusion (Referred to as Zoledronic Acid Infusion in the remainder of this section)**

Please refer to the Summary of Product Characteristics (SmPC) for further details on this product.

#### **How to prepare and administer Zoledronic Acid Infusion**

- Zoledronic Acid 5mg/100ml Solution for Infusion is ready for use.

For single use only. Any unused solution should be discarded. Only clear solution free from particles and discolouration should be used. Zoledronic Acid Infusion must not be mixed or given intravenously with any other medicinal product and must be given through a separate vented infusion line at a constant infusion rate. The infusion time must not be less than 15 minutes. Zoledronic Acid Infusion must not be allowed to come into contact with any calcium-containing solutions. The infusion must be conducted according to standard medical practice.

#### **How to store Zoledronic Acid Infusion**

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.
- The unopened vial does not require any special storage instructions.
- After opening the bottle, the product should be used immediately in order to avoid microbial contamination.

#### **Marketing Authorisation Holder**

SNIGD (UK Limited),  
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#### **Marketing Authorisation Number**

PL 55539/0047  
MA 154/08201

**Date of Revision of Text: October 2021**