PACKAGE LEAFLET: INFORMATION FOR THE USER

Pamidronate Disodium 3 mg/ml and 9 mg/ml Sterile Concentrate

Read all of this leaflet carefully before you start using 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, nurse or pharmacist.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What pamidronate disodium is and what it is used for
2. What you need to know before you use pamidronate disodium
3. How to use pamidronate disodium
4. Possible side effects
5. How to store pamidronate disodium
6. Contents of the pack and other information

1. What pamidronate disodium is and what it is used for

Pamidronate disodium is member of the group of medicines called bisphosphonates. It is useful in medicine because pamidronate disodium binds to bone and reduces bone loss.

This medicinal product may be used in the treatment of a number of disorders associated with bone disease. For example, it is used to help reduce the amount of calcium in the blood and/or reduce bone loss which may occur in certain types of cancer.

Pamidronate disodium is used to treat patients with specific tumours such as bone metastases (secondaries) associated with breast cancer or multiple myeloma which is a type of bone marrow cancer. It can also be used in the prevention of skeletal-related events with a history of bone metastases which can lead to bone pain, radiation or surgery to the bone, spinal cord compression, pathological fractures and hypercalcaemia (high level of calcium in the blood). In addition, it can also be used to treat a bone disorder called 'Paget's disease of bone'.

2. What you need to know before you use pamidronate disodium

Do not use pamidronate disodium

- if you are allergic to pamidronate disodium, medicines of the same group (bisphosphonates) or any of the other ingredients of this medicine (listed in section 6).

Tell your doctor if the above applies to you before this medicine is used.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before using pamidronate disodium if

- you have kidney problems
- you have heart problems
- you have liver problems
- you have had thyroid surgery
- you have been told you have, or think you may have, calcium or vitamin D deficiency

- you have been told you have, or think you may have, low levels of red blood cells (anaemia), white blood cells or platelets. Your doctor may do tests to check for these problems
- you have ear pain, discharge from the ear, and/or an ear infection.
- you have or have had pain, swelling or numbness of the jaw, a feeling of heaviness in the jaw or loosening of a tooth. Your doctor may recommend a dental examination before you start treatment with pamidronate disodium.
- you are having dental treatment or are due to undergo dental surgery, tell your dentist that you are being treated with pamidronate disodium and inform your doctor about your dental treatment.
- you have tumour induced hypercalcemia (calcium levels are above normal in the blood) as your doctor will need to ensure you are adequately hydrated.

While being treated with pamidronate disodium, you should maintain good oral hygiene (including regular teeth brushing) and receive routine dental check-ups.

Contact your doctor and dentist immediately if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, non-healing of sores or discharge, as these could be signs of a condition called osteonecrosis of the jaw.

Patients who are undergoing chemotherapy and/or radiotherapy, who are taking steroids, who are undergoing dental surgery, who do not receive routine dental care, who have gum disease, who are smokers, or who were previously treated with a bisphosphonate (used to treat or prevent bone disorders) may have a higher risk of developing osteonecrosis of the jaw.

Contact your doctor if you experience any thigh, hip or groin pain (see section 4).

Contact your doctor if you experience any bone, joint and/or muscle pain (see section 4).

Before this medicine is given to you, tell your doctor if any of the above applies to you or if you are unsure.

The use of pamidronate disodium in children is not recommended.

Other special warnings

- You must make sure that you do not become dehydrated and maintain urine output while you are being treated with pamidronate disodium, particularly during the initial treatment of tumour induced hypercalcaemia. Talk to your doctor to make sure you are aware how much you must drink.
- As pamidronate disodium may affect your blood (the number of particular cells and the chemistry of the blood), your doctor will monitor for these side effects with blood tests.

Going for a scan?

If you are asked to have a bone scan, tell the doctor doing the scan that you are being treated with pamidronate disodium.

Other medicines and pamidronate disodium

Tell your doctor, nurse or pharmacist if you are using, have recently used or might use any other medicines, including medicines obtained without a prescription.

Special care is needed if you are taking/using other medicines as some could interact with pamidronate disodium, particularly the following:

- Other medicines that may affect the kidneys (Your doctor or nurse will know which drugs these are.)
- Thalidomide (used to treat some cancers).

This medicine should not be used with other bisphosphonate medicines, e.g. zoledronic acid (used to treat osteoporosis and Paget's disease), tiludronic acid (used to treat Paget's disease), or disodium etidronate (used to treat bone metastases associated with breast cancer or multiple myeloma).

Pregnancy, breast-feeding and fertility
If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. If you are pregnant, your doctor will only use this medicine if your life is in danger and no alternative treatment is available. Breast-feeding is not recommended if you are receiving treatment with pamidronate disodium.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Do not drive or use machines if you have blurred or poor vision, or if you experience any other side effect (e.g. drowsiness, dizziness, confusion) which may lessen your ability to do so. If you have pamidronate as an outpatient at a hospital/clinic you should not drive yourself home.

Information about ingredients of this medicine
This medicine contains less than 1 mmol (23 mg) sodium per vial, that is to say essentially "sodium-free".

3. How to use pamidronate disodium

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

This medicine is diluted and then given by infusion (drip) into a vein. The infusion will last from one to several hours depending on the dose.

Dose
Your doctor will work out the correct dose of pamidronate disodium for you and how often it must be given.

The usual dose for each infusion is between 15 and 90 mg.

During treatment you will have blood tests and may be asked to provide urine samples.

If you are given too much or too little pamidronate disodium
This medicine will be given to you by a doctor or nurse. It is unlikely that you will be given too much or too little, however, tell your doctor or nurse if you have any concerns.

4. Possible side effects

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

If the following very rare but serious reaction happens, tell your doctor immediately:

- severe allergic reaction - you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint

You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice or are worried by any of the known side effects listed below. These unwanted side effects occur at the following frequencies:

Very common: may affect more than 1 in 10 people

The most common effects are flu-like symptoms and a mild fever (increase in body temperature which may last for 48 hours) which occur at the start of treatment.

Decrease in the levels of calcium and phosphate in the blood.

Common: may affect up to 1 in 10 people

- pain, redness or swelling at the injection site
- tender or painful veins
- joint or muscle pain, or generalised pain
- temporary increase in bone pain
- conjunctivitis
- feeling or being sick
- headache
- decreased number of white blood cells (lymphocytopenia)
- anaemia
- reduced number of platelets in the blood (thrombocytopenia)
- reduced level of potassium and magnesium in the blood
- tingling sensation in hands and feet
- numbness
- sleeplessness
- high blood pressure
- diarrhoea
- constipation
- skin rash
- increase in blood test values used to measure kidney function
- muscle spasms
- loss of appetite
- stomach pain
- drowsiness
- generalised pain

Uncommon: may affect up to 1 in 100 people

- allergic reactions
- oedema (excess retention of fluid in the body)
- seizures (fits)
- inflammation of the eye (uveitis, iritis)
- itching
- muscle cramps, indigestion
- dizziness, agitation
- tiredness

- low blood pressure (symptoms may include light-headedness, fainting or general weakness)
- death of bone tissue (osteonecrosis)
- renal failure
- pain or inflammation of the jaw
- difficulty in breathing and cough
- changes in liver function which show up in blood tests

Rare: may affect up to 1 in 1,000 people

- kidney problems

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

- flare up of cold sores or shingles (reactivation of Herpes virus)
- a severe or potentially life-threatening allergic reaction
- decreased number of white blood cells (leukopenia)
- increase in levels of potassium and sodium in the blood
- confusion
- hallucinations (seeing things or hearing things that are not there)
- problems with vision/eye pain (scleritis)
- heart failure
- respiratory problems
- lung disease
- blood in urine (Haematuria)
- kidney problems (usually in patients with previous kidney problems)
- 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
- unusual fracture of the thigh bone, particularly in patients on long-term treatment for osteoporosis, 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

Not known: frequency cannot be estimated from the available data

- redness around the eye area
- irregular heart rhythm (atrial fibrillation) has been seen in patients receiving pamidronate. It is currently unclear whether pamidronate causes this irregular heart rhythm. You should report to your doctor if you experience irregular heart rhythm during treatment with pamidronate
- pain in the mouth, teeth and/or jaw, swelling or non-healing sores inside 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 pamidronate disodium or after stopping treatment

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store pamidronate disodium

Keep this medicine out of the sight and reach of children.

Expiry date
Do not use this medicine after the expiry date which is stated on the vial and carton after 'EXP'. Where only a month and year is stated, the expiry date refers to the last day of that month.

Storage conditions
Do not store above 25°C. The vials should be kept in the outer carton, in order to protect from light.

Shelf life after dilution
Unused portions of opened vials must not be stored for later use.

Prepared injections or infusions should be used immediately, however, if this is not possible they can be stored for up to 24 hours at 2-8°C before use.

Visible signs of deterioration
Do not use this medicine if you notice visible particles.

Disposal
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What pamidronate disodium contains
The active substance is pamidronate disodium. Each millilitre (ml) of solution contains either 3 or 9 milligrams (mg) of pamidronate disodium.

The other ingredients are mannitol, phosphoric acid, sodium hydroxide (see section 2 "Information about ingredients of this medicine") and Water for Injections.

What pamidronate disodium looks like and contents of the pack
Pamidronate disodium is a clear, colourless concentrate for solution for infusion which comes in glass containers called vials.

It may be supplied in packs containing:
- 5 x 15 mg/5 ml vials
- 1 x 30 mg/10 ml vial
- 1 x 90 mg/10 ml vial

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Hospira UK Limited
Walton Oaks
Walton-On-The-Hill
Dorking Road
Tadworth

Surrey
KT20 7NS
UK

Manufacturer
Pfizer Service Company BV
Hoge Wei 10
1930 Zaventem
Belgium

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Pamidronate Disodium 3 mg/ml and 9 mg/ml Sterile Concentrate

The following information is intended for medical or healthcare professionals only

Further to the information included in section 3, practical information on the preparation/handling of the medicinal product is provided here.

Incompatibilities
Pamidronate will form complexes with divalent cations and should not be added to calcium-containing intravenous solutions such as Ringer's solution.

Instructions for use and handling
For intravenous use as infusion only.

Pamidronate disodium must never be given as a bolus injection (see section 4.4 of SmPC). The solution must be diluted before use and must be infused slowly.

The concentration of pamidronate disodium in the infusion solution should not exceed 90 mg/250 ml.

Do not use solution if particles are present.

Any portion of the contents remaining after use should be discarded.

In use storage precautions
Following dilution in 0.9% sodium chloride and 5% glucose infusion solutions, chemical and physical in-use stability has been demonstrated for 24 hours at temperatures not exceeding 25°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C, unless dilution has taken place in controlled and validated aseptic conditions.