

PAMISOL™

disodium pamidronate (pa-mi-DROE-nate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PAMISOL. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PAMISOL against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What PAMISOL is used for

This medicine is to treat:

- cancer of the bone that has spread from breast cancer or advanced multiple myeloma (a cancer of the bone marrow)
- high calcium levels in the blood due to cancer
- Paget's disease (a disease in which sections of bone break down excessively and are repaired incorrectly by the body).

This medicine belongs to a group of medicines called bisphosphonates.

It works by binding to bones and preventing them from being broken down excessively. This reduces the amount of calcium released into the blood. It can also reduce bone pain, prevent fractures (breaks) and reduce

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children.

Before you are given PAMISOL

When you must be given not it

You must not be given PAMISOL you have an allergy to:

- any medicine containing disodium pamidronate
- any of the ingredients listed at the end of this leaflet
- any other bisphosphonate medicines.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Tell your doctor if you are planning to have dental treatment. You may need to have any dental treatment completed before starting PAMISOL. You should not be given this medicine if you are pregnant.

It may affect your developing baby if you are given it during pregnancy.

You should not be given this medicine if you are breast-feeding.

The active ingredient in PAMISOL may pass into breast milk and there is a possibility that your baby may be affected.

This medicine should not be used for children.

Safety and effectiveness in children have not been established.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney disease
- heart disease
- liver disease
- thyroid surgery
- hyperparathyroidism (overactive parathyroid gland).
- calcium deficiency or vitamin D deficiency
- pain, swelling or numbness of the jaw or a heavy jaw feeling or loosening of a tooth

- low levels of red blood cells (anaemia), white blood cells or platelets

Your doctor may do tests to check for these problems.

- ear pain, discharge from the ear, and/or an ear infection
- 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.

Tell your doctor if 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.

Tell your doctor if you currently have a fever.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start treatment with PAMISOL.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a

prescription from your pharmacy, supermarket or health food shop.

Some medicines and PAMISOL may interfere with each other. These include:

- other bisphosphonates (such as DBL Zoledronic Acid, Zometa, Aclasta, Actonel, Fosamax)
- calcitonin, a hormone used to reduce the amount of calcium in the blood. These medicines may be affected by PAMISOL or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.
- thalidomide, a medicine used to treat a number of cancers
- medicines that may have side effects on your kidneys.

These medicines may be affected by PAMISOL, or may affect how well it works. You may need different amounts of your medicine, or you may need to use different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How PAMISOL is given

How much is given

Your doctor will decide what dose you will receive and for how long you will receive it for. This depends on your condition and other factors, such as your weight.

How is given

This medicine is given as an infusion (drip) into your veins, usually over 2 hours. It must only be given by a doctor or nurse.

If you are given too much (overdose)

As PAMISOL is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any severe side effects after being given this medicine, tell your doctor or nurse immediately.

You may need urgent medical attention.

Symptoms of an overdose may include unusual light headedness, dizziness or faintness; numbness or tingling; muscle cramps, convulsions or twitching; changes in heart rate (fast, slow or irregular).

If you think you may have been given too much PAMISOL, immediately contact the Poisons Information Centre on 13 11 26 for advice.

While you are being given PAMISOL

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking PAMISOL.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Tell your radiologist you are on this medicine before you have any bone scans

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Tell your doctor about any pain or unusual feeling in your teeth or gums or any dental infections. Cancer treatments can affect your whole body, including your teeth and gums.

Things to be careful of

Be careful driving or operating machinery until you know how PAMISOL affects you.

This medicine may cause dizziness or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are being treated with this medicine.

If you drink alcohol, dizziness may be worse.

If you are given this medicine as an outpatient at hospital, you must not drive yourself home from the hospital.

If dizziness or drowsiness occurs, it may last for up to 24 hours. It rarely lasts for more than 24 hours.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PAMISOL.

This medicine helps most people with excessive bone loss, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- ‘flu-like’ symptoms
- fever, chills or shivering
- generally feeling unwell
- tiredness, sleepiness or drowsiness
- headache
- confusion, seeing, feeling or hearing things that are not there, difficulty sleeping
- pain, redness or swelling at the injection site
- bone or muscle pain
- nausea, vomiting, diarrhoea, constipation, indigestion and/or changes in your usual bowel habit
- upset stomach, abdominal pain, loss of appetite
- agitation
- difficulty in breathing with wheezing and coughing.

- changes in liver function which show up in blood tests
- reduced level of potassium, phosphorus, sodium and magnesium in the blood which show up in blood tests.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- seizures (convulsions)
- signs of an allergic reaction, such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.
- unusual light headedness, dizziness or faintness, tingling or burning sensation anywhere on the body, numbness or cramps, twitching or muscle spasms
- swelling of the ankles, feet or lower legs
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- difficulty urinating or blood in the urine
- muscle, bone and/or joint pain
- newly developed anaemia and/or blood disorders, or infection of any kind
- irregular heart rhythm or changes in heart rhythm and/or changes in blood pressure

- irritated eyes, itchy, red or swollen eyes, sensitivity to light, blurred vision or pain in the eye
- 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, loosening of a tooth, or infection after tooth extraction or other work that involves drilling into the jaw.

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 PAMISOL or after stopping treatment.

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After treatment with PAMISOL

Storage

PAMISOL will be stored in the pharmacy or in the hospital.

The injection is kept in a cool dry place, protected from light, where the temperature stays below 25C.

Product description

What it looks like

PAMISOL is a clear colourless solution.

Ingredients

PAMISOL contains 3, 6, or 9 mg/mL of disodium pamidronate as the active ingredient.

It also contains:

- mannitol
- phosphoric acid or sodium hydroxide.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Pfizer Australia Pty Ltd

Sydney, NSW

Toll Free Number: 1800 675 229.

www.pfizer.com.au.

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Australian Registration Numbers

PAMISOL 15 mg /5 mL - AUST R 75106.

PAMISOL 30 mg/10 mL - AUST R 75107.

PAMISOL 60 mg /10 mL - AUST R 75108.

PAMISOL 90 mg/10mL - AUST R 75109.