

## 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 being given PAMISOL™ against the benefits they expect it will have for you.

**If you have any concerns about being given this medicine, ask your doctor or pharmacist.**

**Keep this leaflet.**

You may need to read it again.

#### What PAMISOL™ is used for

This medicine is used in the treatment of:

- 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 the need for radiation therapy of cancers that have spread to the bone.

**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.

This medicine 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 not be given it*

**You must not be given PAMISOL™ if 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.

**If you are not sure whether you should be given 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 are planning to have dental treatment. You may need to**

**have any dental treatment completed before starting PAMISOL™.**

**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.

**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 them before you are given PAMISOL™.**

*Taking other medicines*

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy 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 etidronate or disodium clodronate)
- 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 medicine, or you may need to use different medicines.

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

#### How PAMISOL™ is given

*How much is given and for long*

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 it 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.

*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).

In case of overdose, immediately contact the Poisons Information Centre for advice. (In Australia, call 13 11 26; in New Zealand call 0800 764 766.)

#### 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 being given PAMISOL™.**

**Tell any other doctors, dentists, and pharmacists who are treating you that you are being given this medicine.**

**If you are going to have surgery, tell your surgeon or anaesthetist that you are being given this medicine.**

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

**If you become pregnant while you are being treated with 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.

Tell your doctor immediately if you become pregnant whilst having treatment with PAMISOL™.

*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 nurse as soon as possible if you do not feel well while you are being given 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 treatment 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 nurse if you notice any of the following and they worry you:**

- ‘flu-like’ symptoms
- fever, chills or shivering
- generally feeling unwell
- tiredness, drowsiness
- headache
- dizziness or light-headedness
- pain, redness or swelling at the injection site
- bone or muscle pain
- nausea, vomiting, diarrhoea, constipation
- irritated eyes.

These side effects are usually mild.

**Tell your doctor or nurse immediately if you notice any of the following:**

- 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.
- tingling or burning sensation anywhere on the body
- numbness or cramps
- twitching or muscle spasms
- swelling of the ankles, feet or lower legs
- difficulty urinating or blood in the urine
- problems with your eyesight.
- jaw-bone problems, which may include delayed healing and infection after tooth extraction or other work that involves drilling into the jaw.
- newly developed muscle, bone and/or joint pain
- newly developed anaemia and/or blood disorders, or infection of any kind
- changes in heart rhythm and/or changes in blood pressure
- nausea, vomiting and/or changes in your usual bowel habit
- headache

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

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

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

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## After using PAMISOL™

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### *Storage*

PAMISOL™ will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

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## Product description

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### *What it looks like*

PAMISOL™ is a clear colourless solution.

### *Ingredients*

PAMISOL™ contains disodium pamidronate as the active ingredient. It also contains:

- mannitol
- phosphoric acid
- sodium hydroxide.

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

PAMISOL™ is available in the following presentations and pack size:

- 15 mg disodium pamidronate/5 mL (single pack)  
AUST R 75106
- 30 mg disodium pamidronate/10 mL (single pack)  
AUST R 75107
- 60 mg disodium pamidronate/10 mL (single pack)  
AUST R 75108
- 90 mg disodium pamidronate/10mL (single pack)  
AUST R 75109

### *Sponsor*

PAMISOL™ is supplied by:

#### **Australian Sponsor**

Hospira Australia Pty Ltd  
ABN 58 097 064 330  
Level 3  
500 Collins Street  
Melbourne VIC 3000  
Australia

#### **New Zealand Sponsor:**

Hospira NZ Limited  
58 Richard Pearse Drive  
Airport Oaks, Mangere 2022  
Auckland  
New Zealand

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