Pamisol™

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being treated with Pamisol?

Pamisol contains the active ingredient pamidronate disodium. Pamisol is used to treat bone cancer, high blood calcium levels or a bone disease where bone breaks down excessively and is incorrectly repaired by the body.

For more information, see Section <u>1. Why am I being</u> <u>treated with Pamisol?</u> in the full CMI.

2. What should I know before treatment with Pamisol?

Pamisol should not be used if you have ever had an allergic reaction to pamidronate disodium, any of the ingredients listed at the end of the CMI, other similar types of medicine, or are pregnant or breastfeeding.

Talk to your doctor if you have any other medical conditions or take any other medicines.

For more information, see Section 2. What should I know before treatment with Pamisol? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Pamisol and affect how it works. Examples include other bisphosphonates, medicines to slow down or prevent bone loss; calcitonin, a medicine to reduce calcium in the blood; thalidomide, a medicine used to treat a number of cancers; medicines that may have side effects on your kidneys.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is Pamisol given?

Your doctor will give you Pamisol as a slow drip into a vein and decide how much you will be given and for how long.

More instructions can be found in Section <u>4. How is</u> <u>Pamisol given?</u> in the full CMI.

5. What should I know during treatment with Pamisol?

Things you should do	Tell or check with your doctor if you have kidney, heart or liver disease;
	thyroid surgery; overactive parathyroid; calcium or

	vitamin D deficiency; pain, swelling or numbness of the jaw, heavy jaw or loose teeth; low levels of red blood cells (anaemia), white blood cells or platelets from blood tests; ear pain, discharge and/or ear infection; thigh or groin pain.
	Remind any doctor, surgeon, anaesthetist, pharmacist or dentist you visit that you are being treated with Pamisol.
Driving or using machines	Pamisol may cause dizziness or drowsiness and may affect your ability to drive a car or operate machinery.
Drinking alcohol	Drinking alcohol while you are being treated with Pamisol may cause dizziness to become worse.
Looking after your medicine	The hospital will store and dispose of the medicine.

For more information, see Section <u>5. What should I know</u> during treatment with Pamisol? in the full CMI.

6. Are there any side effects?

Possible side-effects include: seizures; signs of an allergic reaction (shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of body, rash, itching, hives); light headedness, dizziness, faintness; a tingling/burning sensation, numbness/cramps, twitching/muscle spasms; difficulty urinating, blood in urine, vomiting, nausea; anaemia and/or other blood disorders, or infection, bleeding and bruising more easily; irregular or changes to heart rhythm; irritated, 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 sores inside the mouth or jaw, discharge, numbness or a feeling of heaviness in the jaw, loosening of a tooth, infection; ear pain, discharge or ear infection; thigh or groin pain; pain/ pressure in the head with hearing or vision changes; breathlessness, swollen feet or lower legs. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Pamisol™

Active ingredient(s): pamidronate disodium (pa-mi-DROE-nate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Pamisol. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Pamisol.

Where to find information in this leaflet:

- 1. Why am I being treated with Pamisol?
- 2. What should I know before treatment with Pamisol?
- 3. What if I am taking other medicines?
- 4. How is Pamisol given?
- 5. What should I know during treatment with Pamisol?
- 6. Are there any side effects?
- 7. Product details

1. Why am I being treated with Pamisol?

Pamisol contains the active ingredient pamidronate disodium. Pamisol belongs to a group of medicine called bisphosphonates. Bisphosphonates bind to bone and reduce the rate at which it is broken down. This

Pamisol™

helps strengthen bones by preventing the loss of calcium and this reduces the high levels of calcium in the blood..

In some cancers there can be an excessive breakdown of bone. As this happens, calcium is lost from the bone and seeps into the blood, leading to higher than normal levels of calcium in the blood. Pamisol is used to ease bone pain or to reduce high calcium levels in the blood associated with some cancers.

In Paget's disease of bone, pamidronate disodium works on bones to make them stronger and help prevent bone thickening

2. What should I know before treatment with Pamisol?

Warnings

You should not be given Pamisol if you:

- are allergic to pamidronate disodium, or any of the ingredients listed at the end of this leaflet.
- are allergic to similar types of medicines that slow down or prevent bone loss.
- are pregnant or breastfeeding.

Check with your doctor if you:

- kidney disease.
- heart disease.
- liver disease.

- thyroid surgery.
- overactive parathyroid.
- 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 and/or an ear infection

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You must not be given this medicine if you are pregnant or breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements 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 risedronic acid or alendronic acid), medicines to slow down or prevent bone loss.

- calcitonin, medicine to reduce calcium in the blood.
- thalidomide, medicine to treat a number of cancers.
- medicines that may have side effects on your kidneys.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Pamisol

4. How is Pamisol given?

How much will be given

Pamisol is given as a slow drip into your vein. Your doctor will decide what dose you will receive and for how long you will receive it. This depends on your condition and other factors, such as your weight or if you have kidney problems.

If you are given too much Pamisol

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 such as tingling or numbness of the hands or feet, muscle cramps, dizziness or lightheadedness, tell your doctor or nurse immediately. You may need urgent medical attention.

5. What should I know during treatment with Pamisol?

Things you should do

Tell your doctor immediately:

- about any pain or unusual feeling in your teeth or gums or any dental infections.
- about any ear pain, discharge or ear infection.
- If you experience thigh or groin pain as this may indicate a type of fracture to your leg.
- Remind any doctor, pharmacist or dentist you visit that you are using Pamisol. It is not advised to have invasive dental procedures while being treated with Pamisol.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
- Take any vitamins or supplements your doctor has asked you to take while being treated with Pamisol.
- Have any tests that your doctor asks you to have while being treated with Pamisol as these are important to monitor your health.

Things you should not do

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Pamisol affects you.

This medicine may cause dizziness or drowsiness in some people. If you drink alcohol, dizziness may be worse.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

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.

Drinking alcohol

Drinking alcohol while you are being treated with this medicine may cause dizziness to become worse.

Looking after your medicine

Pamisol is stored in a hospital which is responsible for storing and disposing of any unused product correctly.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Side effects

Side effects	What to do
 "flu-like" symptoms, fever, chills or shivering generally feeling unwell 	Speak to your doctor if you have any of these less serious side effects and they worry you.
 appearance of "cold sores", blisters around face, mouth or genital areas tiredness, sleepiness or drowsiness 	
 headache agitation, confusion, seeing, feeling or hearings things that are not there, difficulty sleeping pain, redness or swelling at the injection site rash, itching bone, muscle or joint pain; general pain 	

Side effects What to do upset stomach or pain, loss of appetite, nausea, vomiting, diarrhoea, constipation, indigestion and/or changes in bowel habit. seizures (convulsions) Call your doctor straight away or go straight signs of an allergic to the Emergency reaction, such as Department at your shortness of breath. nearest hospital if you wheezing or difficulty notice any of these breathing; swelling of serious side effects. the face, lips, tongue or other parts of the body; rash, itching or hives on the skin anaemia and/or blood disorders, which may cause tiredness, headaches, dizziness, shortness of breath when exercising. looking pale; frequent infections such as fevers, severe chills. sore throat or mouth ulcers; bleeding or

Side effects	What to do
bruising more easily than usual	
 irregular or changes to heart rhythm (fluttering or palpitations) 	
 unusual light headedness, dizziness or faintness, tingling or burning sensation, numbness or cramps, twitching or muscle spasms 	
 swelling of the ankles, feet or lower legs 	
 kidney problems with difficulty urinating, blood in urine, can be with drowsiness, breathlessness, vomiting or nausea. irritated, 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- 	

Side effects What to do healing sores inside the mouth or jaw, discharge, numbness or a feeling of heaviness in the jaw, loosening of a tooth, or infection ear pain, discharge, or ear infection • thigh or groin pain as this may indicate a type of fracture to your leg • a feeling of pressure in the head, which may be accompanied by headache, abnormal sounds in ears, and/or visual changes. heart problems which may cause breathlessness, particularly when lying down, swelling of the feet or legs Changes in liver function; reduced blood potassium, phosphorus, calcium and magnesium levels;

Side effects	What to do
or elevated sodium and magnesium levels which will show up when you have a blood test.	

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

Reporting side effects

After you have received medical advice for any sideeffects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/safety/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Pamisol contains

Active ingredient	pamidronate disodium
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(main ingredient)	
Other ingredients	mannitol, phosphoric acid
(inactive ingredients)	or sodium hydroxide.

You should not be given this medicine if you are allergic to any of these ingredients.

Pamisol does not contain lactose, sucrose, gluten, tartrazine or other azo dyes.

What Pamisol looks like

Pamisol is a clear, colourless solution that will be diluted before use.

Australian Registration Number

Pamisol 15 mg /5 mL glass vial - AUST R 75106.

Pamisol 30 mg/10 mL glass vial - AUST R 75107.

Pamisol 60 mg /10 mL glass vial - AUST R 75108.

Pamisol 90 mg/10 mL glass vial - AUST R 75109.

Who distributes Pamisol

Pfizer Australia Pty Ltd

Sydney NSW.

Toll Free Number: 1800 675 229.

www.pfizermedicalinformation.com.au

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