

**PART III: CONSUMER INFORMATION****Pr Pamidronate Disodium Omega  
(Pamidronate disodium for injection)**

Solution for Injection

3 mg / mL, 6 mg / mL and 9 mg / mL

This leaflet is part III of a three-part "Product Monograph" published when Pamidronate Disodium Omega was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Pamidronate Disodium Omega. Contact your doctor or pharmacist if you have any questions about the drug.

Please read this information carefully before starting treatment with Pamidronate Disodium Omega. Keep this leaflet. You may need to read it again. This medicine has been prescribed for your current medical problem only. Do not give it to other people or use it for any other illnesses.

**ABOUT THIS MEDICATION****What the medication is used for:**

Pamidronate Disodium Omega is used to treat:

- high calcium levels in the blood due to cancer (tumour-induced hypercalcemia);
- bone tumours resulting from the spread of tumours at other sites and multiple myeloma;
- Paget's disease of bone in patients with symptoms.

**What it does:**

Pamidronate Disodium Omega is a bisphosphonate which strongly binds to the bone and slows down the rate of bone change. This helps to reduce the amount of calcium in the blood and bone loss.

**When it should not be used:**

You should not be given Pamidronate Disodium Omega if you are:

- allergic to Pamidronate Disodium Omega or other bisphosphonates;
- pregnant;
- breast-feeding.

If this applies to you, **tell your doctor before being given Pamidronate Disodium Omega**. If you think you may be allergic, ask your doctor for advice.

**What the medicinal ingredient is:**

Pamidronate disodium.

**What the important non-medicinal ingredients are:**

Mannitol, phosphoric acid, and sodium hydroxide.

**What dosage form it comes in:**

Pamidronate Disodium Omega is available as a solution in vials. Each vial contains 30 mg, 60 mg or 90 mg of pamidronate disodium. It is given as an infusion into a vein after appropriate dilution. Available in single dose vials of 10 mL.

**WARNINGS AND PRECAUTIONS****Serious Warnings and Precautions**

Possible serious side effects with the use of pamidronate disodium include:

- Osteonecrosis of the jaw (a severe bone disease that affects the jaw)
- Worsening of kidney function. Pamidronate Disodium Omega should not be given to patients with severely reduced kidney function.
- Single doses of Pamidronate Disodium Omega should not exceed 90 mg and must be given at the recommended infusion rates.

**Before Starting Treatment with Pamidronate Disodium Omega**

Be sure that you have discussed Pamidronate Disodium Omega treatment with your doctor. You may only be given Pamidronate Disodium Omega after a full medical examination. Your doctor may also request a dental examination with any necessary preventive dentistry carried out prior to treatment with Pamidronate Disodium Omega. This may be required since some patients have experienced side effects following dental procedures (such as tooth extraction) while on treatment with Pamidronate Disodium Omega; as well since patients with dental infections or periodontal disease (disease affecting surrounding tissues of a tooth) may be at increased risk of problems with their jaw bones following dental procedures (such as tooth extraction) while on treatment with Pamidronate Disodium Omega (see **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**).

**BEFORE you use Pamidronate Disodium Omega, talk to your doctor or pharmacist if you:**

- have a heart, liver or kidney problem;
- suffer from calcium or vitamin D deficiency (for example owing to your diet or as a result of digestive problems);
- have any dental problems or any dental procedures planned in the future;

- had or have pain, swelling or numbness of the jaw or a “heavy jaw feeling” or loosening of tooth;
- have an eye problem;
- have sores in the mouth. This can lead to osteonecrosis of the jaw. Your doctor may check if you:
  - smoke
  - have or have had teeth and/or gum disease
  - have dentures that do not fit well
  - have other relevant medical conditions at the same time such as a low red blood cell count (called anemia) or if your blood cannot form clots in the normal way.

Your doctor may tell you to stop taking Pamidronate Disodium Omega until all sores in your mouth are healed.

**During Treatment with Pamidronate Disodium Omega:**

Ensure sufficient intake of liquids prior to infusions as directed by your doctor as this will help to prevent dehydration.

Your treatment may need to be supplemented with calcium and vitamin D to prevent low calcium levels.

It is important that your doctor checks your progress at regular intervals. Since bisphosphonates (the class of drugs to which Pamidronate Disodium Omega belongs) may cause damage to the kidneys (worsening of kidney function including kidney failure and death have been reported very rarely with the use of Pamidronate Disodium Omega), he or she may want to take repeated blood tests, especially after starting your treatment with Pamidronate Disodium Omega and before each additional dose.

Your doctor may also want to take other repeated blood tests if you have low level of white blood cells, red blood cells and/or platelets.

**Tooth Extraction and Other Dental Procedures**

If possible, you should not undergo tooth extraction or other dental procedures (excluding regular dental cleaning) while you are receiving treatment with Pamidronate Disodium Omega. Please consult your doctor if a dental procedure (excluding regular dental cleaning) is required while you are receiving treatment with Pamidronate Disodium Omega. It is important to maintain good dental hygiene; regularly scheduled dental examinations are recommended.

**Pregnancy or Breast-Feeding**

You should tell your doctor if you:

- are pregnant, or planning to become pregnant before you receive Pamidronate Disodium Omega. It should not be given during pregnancy.

- are breast-feeding, or intend to breast-feed. Mothers treated with Pamidronate Disodium Omega should not breast-feed their babies.

**Women of Child-bearing Potential**

You must use highly effective contraception during treatment.

**Use in Children, Adolescents and Elderly Patients**

Pamidronate Disodium Omega has not been adequately studied in children or adolescents. Until further experience is gained, Pamidronate Disodium Omega is only recommended for use in adult patients.

Elderly patients at the age of 65 years or older may be safely treated with Pamidronate Disodium Omega, provided that they do not have a serious heart, liver or kidney problem. Ask your doctor if you have any questions about this.

**If You Drive A Vehicle or Use Machinery**

Pamidronate Disodium Omega may cause some patients to become sleepy or dizzy, especially immediately after the infusion. If this happens, you should not drive or use machinery or perform other tasks that need full attention.

**INTERACTIONS WITH THIS MEDICATION**

Before starting Pamidronate Disodium Omega treatment, talk to your doctor about any other medicines that you are using or intend to use. It is especially important that your doctor knows if you are being treated with another bisphosphonate, calcitonin, thalidomide, or vitamin supplements.

**PROPER USE OF THIS MEDICATION**

Pamidronate Disodium Omega can be given only by slow infusion into a vein. The dose will be decided by your doctor.

**Usual Dose**

- Tumour-induced hypercalcemia: 30 to 90 mg
- Bone tumours or multiple myeloma: 90 mg every 3 to 4 weeks
- Paget’s disease: 30 to 60 mg in one infusion

An infusion may last one or more hours, depending on the dose given and the condition of your kidney. You may receive additional saline solution for re-hydration.

**Overdose**

In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medicines, patients treated with Pamidronate Disodium Omega may experience side effects.

**Very common side effects:**

*These side effects may affect more than 1 in 10 patients.*

- Short-lasting fever and flu-like conditions with chills, sometimes together with a feeling of tiredness and general discomfort.
- Low level of calcium and phosphate in the blood.
- Tiredness, lack of energy.

If any of these affects you severely, **tell your doctor.**

**Common side effects:**

*These side effects may affect between 1 and 10 in every 100 patients.*

- Low level of red blood cells
- Low level of white blood cells
- Low level of platelets (cells in the blood that help stop bleeding)
- Headache
- Sleep disturbances
- Eye irritation
- High blood pressure
- Irregular heart rhythm (atrial fibrillation)
- Vomiting
- Loss of appetite
- Abdominal pain
- Diarrhea
- Constipation
- Stomach pain
- Sickness (nausea)
- Skin rash
- Generalised pain
- Low levels of potassium and magnesium in the blood
- Short-lasting muscle or joint pain

If any of these affects you severely, **tell your doctor.**

**Uncommon side effects:**

*These side effects may affect between 1 and 10 in every 1000 patients.*

- Agitation
- Muscle cramps
- Low blood pressure

- Itching
- Abnormal liver function test
- Problems with jaw bones (osteonecrosis of the jaw)

If any of these affects you severely, **tell your doctor.**

The following side effects have been reported in some patients taking pamidronate disodium:

- Painful red eye and/or swollen eye, painful eyeball, photophobia, excessive tearing or decreased vision. You should report these to your doctor as they may indicate more serious complications.
- Problems with jaw bones (osteonecrosis of the jaw). Dental hygiene is an important element of your overall patient care and is important in possibly decreasing the chances of this type of problem occurring. Removable dentures should fit properly and should be removed at night. Please consult with your doctor if you experience pain in your mouth, teeth or jaw, or if your gums or mouth heals poorly. Any non-healing of a dental extraction site or chronic dental infection should be assessed. If you notice any other effects, tell your doctor immediately. In addition, if possible, you should not undergo tooth extraction or other dental procedures (excluding regular dental cleaning) while on therapy with Pamidronate Disodium Omega. Please consult your doctor if a dental procedure (excluding regular dental cleaning) is required while you are receiving treatment with Pamidronate Disodium Omega (see **WARNINGS and PRECAUTIONS: Tooth Extraction and Other Dental Procedures**).

Some side effects could be serious and might need immediate medical attention.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / Effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
	Only if severe	In all cases	
<b>Common</b>			
• Low level of blood platelets which, if severe, may cause spontaneous bleeding and bruising			√

• Low level of white blood cells which, if severe, may cause fever, mouth ulcers, infections of the throat, ears, skin, or lungs (pneumonia)			√
• Tingling or numbness and muscle spasms and twitching, symptoms of low level of calcium			√
• Irregular heart rhythm (atrial fibrillation)			√
<b>Uncommon</b>			
• Severe allergic reaction which causes difficulty in breathing, swollen lips and tongue or a sudden fall in blood pressure			√
• Osteonecrosis of the jaw (numbness or feeling of heaviness in the jaw, poor healing of the gums especially after dental work, loose teeth, exposed bone in mouth, pain in the mouth, teeth or jaw, swelling or gum infections, bad breath)			√
• Seizures			√
• Kidney failure (changes in urine colour or absence of urine production, changes in kidney function laboratory tests, lower back pain, fatigue, nausea, loss of appetite)			√
• Kidney damage, including deterioration of pre-existing renal disease			√

• High level of sodium and potassium in the blood			√
<b>Unknown</b>			
• Painful eyeball and/or swollen eyes			√

This is not a complete list of side effects. If you have any unexpected side effects after receiving Pamidronate Disodium

**Reporting Side Effects**

**HOW TO STORE IT**

use or health products to Health Canada by:

- Visiting the Web page on [Adverse Reaction Reporting](#) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

Omega, contact your doctor or pharmacist.

**MORE INFORMATION**

Store between 15 and 25°C. Do not freeze. The products are for single use only and unused portions should be discarded.

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

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, Omega Laboratories, Limited, at:

Montreal: (514) 335-0310 or 1-800-363-0584  
 By mail: Omega Laboratories Limited  
 11 177 Hamon  
 Montreal, QC H3M 3E4

This leaflet was prepared by Omega Laboratories Limited

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**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / Effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical attention
	Only if severe	In all cases	
<b>Rare</b>			
• Protein in urine			√
<b>Very rare</b>			
• Anaphylactic shock			√
• Blood in urine			√
• Heart disease characterized by breathlessness and fluid retention in the body			√
• Reactivation of Herpes simplex and Herpes zoster			√
• Confusion, visual hallucinations			√