

CONSUMER INFORMATION

Pr **AREDIA***

(pamidronate disodium)

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

Please read this information carefully before starting treatment with AREDIA* (pamidronate disodium). Keep this leaflet. You may need to read it again.

ABOUT THIS MEDICATION

What the medication is used for:

AREDIA* 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:

AREDIA* is a bisphosphonates 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 AREDIA* if you:

- are allergic to AREDIA* or other bisphosphonates;
- are pregnant;
- are breast-feeding.

What the medicinal ingredient is:

Pamidronate disodium.

What the important nonmedicinal ingredients are:

Mannitol and phosphoric acid.

What dosage forms it comes in:

AREDIA* is available as a powder in vials. One vial contains 30 mg or 90 mg of pamidronate disodium. AREDIA* is given as an infusion into a vein after appropriate dilution.

WARNINGS AND PRECAUTIONS

Before starting treatment with AREDIA*

Be sure that you have discussed AREDIA* treatment with your doctor. You may only be given AREDIA* after a full medical examination. Your doctor may also request a dental examination

with any necessary preventive dentistry carried out prior to treatment with AREDIA*. This may be required since some patients have experienced side effects following dental procedures (such as tooth extraction) while on treatment with AREDIA*; 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 AREDIA* (see **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**).

BEFORE you use AREDIA* 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 a tooth.

During treatment with AREDIA*

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 AREDIA* 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 AREDIA*), he or she may want to take repeated blood tests, especially after starting your treatment with AREDIA* and before each additional dose.

If possible, you should not undergo tooth extraction or other dental procedures (excluding regular dental cleaning) while you are receiving treatment with AREDIA*. Please consult your doctor if a dental procedure (excluding regular dental cleaning) is required while you are receiving treatment with AREDIA*. 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 AREDIA*. AREDIA* should not be given during pregnancy.
- are breast-feeding, or intend to breast feed. Mothers treated with AREDIA* should not breast-feed their babies.

Use in Children and Elderly Patients

So far children have not been treated with AREDIA*. Until further experience is gained, AREDIA* is only recommended for use in adult patients.

Elderly patients at the age of 65 years or older may be safely treated with AREDIA*, 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

AREDIA* 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.

Other Important Information

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.

INTERACTIONS WITH THIS MEDICATION

Before starting AREDIA* 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

AREDIA* can be given only by slow infusion into a vein. The dose will be decided by your doctor.

Usual dose:

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Patients taking AREDIA* may experience side effects, although not everybody gets them.

The most common (more than 1 in 10 patients) side effects are:

- short-lasting fever and flu-like condition with chills, sometimes together with a feeling of tiredness and general discomfort.
- Low level of phosphate in the blood.

Irregular heart rhythm (atrial fibrillation) has been reported in patients receiving AREDIA*. You should report to your doctor if you experience irregular heart beat during treatment with AREDIA*.

Less common (affects between 1 and 10 in every 100 patients) side effects include:

- Low level of red blood cells
- Headache
- Sleep disturbances
- Constipation
- Stomach pain
- Sickness

- Eye irritation
- High blood pressure
- Vomiting
- Loss of appetite
- Abdominal pain
- Diarrhea
- Skin rash
- Pain
- Changes in blood test results
- Short-lasting muscle or joint pain
- Redness and swelling at the site of infusion

Other side effects not listed above may also occur in some patients. Some of these include: agitation, dizziness, tiredness, muscle cramps, low blood pressure, itching, and abnormal liver function test. Eye pain, redness, photophobia, excessive tearing or decreased vision should be reported to your physician as they may indicate more serious eye complications which have been associated with AREDIA*.

Some patients have reported problems with their jaw bones while receiving cancer treatments that include AREDIA*. Dental hygiene is an important element of your overall cancer 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 AREDIA*. Please consult your doctor if a dental procedure (excluding regular dental cleaning) is required while you are receiving treatment with AREDIA*.

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 call your doctor or pharmacist
	Only if severe	In all cases	
Common			
• Spontaneous bleeding and bruising due to low level of blood platelets			√
• Low level of lymphocytes, a specific type of white blood cells with important functions in the immune system			√
• Tingling or numbness and muscle spasms and twitching, symptoms of low level of calcium			√

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
<p>Uncommon</p> <ul style="list-style-type: none"> • 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 • Hematuria (blood in urine), kidney damage, including deterioration of pre-existing renal disease 			<p>√</p> <p>√</p> <p>√</p> <p>√</p> <p>√</p>
<p>Very rare</p> <ul style="list-style-type: none"> • Anaphylactic shock • Low level of white blood cells • Heart disease characterized by breathlessness and fluid retention in the body • Reactivation of Herpes simplex and Herpes zoster • Confusion, visual hallucinations 			<p>√</p> <p>√</p> <p>√</p> <p>√</p> <p>√</p>

This is not a complete list of side effects. If you have any unexpected side effects after receiving AREDIA*, contact your doctor or pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

1. Report online at www.healthcanada.gc.ca/medeffect
2. Call toll-free at 1-866-234-2345
3. Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9
 Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of the side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
<http://www.novartis.ca>
 or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc, at:
 1-800-363-8883

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HOW TO STORE IT

Protect vials from heat (store below 30°C). Store in the original package.

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

AREDIA* should not be used after the expiry date shown on the package label. Remember to take back any unused medicine to your pharmacist.