

# Aredia(R)

disodium pamidronate

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Aredia.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

**You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from [www.novartis.com.au](http://www.novartis.com.au).**

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you having Aredia against the benefits they expect it will provide.

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

**Keep this leaflet.**

You may need to read it again.

### What Aredia is used for

Aredia is used to lower the amount of calcium in the blood when it becomes too high, as may happen in some forms of cancer.

Some cancers can speed up normal changes in bone so that the amount of calcium released from the bones into the blood is increased. Aredia belongs to a group of medicines called bisphosphonates, which strongly bind to bone. These medicines slow down the rate of bone change and help to restore the amount of calcium in the blood to normal.

Aredia can also be used in other conditions with increased bone changes or pain, including Paget's disease, advanced cancer of the bone marrow (called multiple myeloma) and advanced breast cancer where the cancer has 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 purpose.

Aredia is only available with a doctor's prescription. It is not addictive.

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

### Before you have Aredia

#### When you must not have it

**Do not have Aredia if you have ever had an allergic reaction to:**

- \* disodium pamidronate (the active ingredient in Aredia) or any of the other ingredients listed at the end of this leaflet

- \* any other bisphosphonate medicine

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 are allergic to other bisphosphonate medicines, talk to your doctor.**

Other bisphosphonate medicines can cause breathing difficulties in people with asthma who are allergic to aspirin.

**Do not have Aredia if you are pregnant.**

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

**Do not breast-feed if you are having treatment with Aredia.**

It is not known if the active ingredient, disodium pamidronate, passes into the breast milk and could affect your baby.

**Do not have Aredia after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

In that case, return the medicine to your pharmacist.

#### Before you start to have it

**Tell your doctor if:**

- \* you have a kidney or liver problem
- \* you have a heart condition
- \* you have asthma and are also allergic to aspirin

- \* you have had surgery on your thyroid
- \* you have a calcium deficiency or vitamin D deficiency (e.g. from your diet or as a result of digestive problems)
- \* If you had or have pain in the teeth, gums or jaw, swelling or numbness of the jaw or a "heavy jaw feeling" or loosening of a tooth.

**It is advisable to have a dental check-up before starting on Aredia. Tell your dentist you may be receiving Aredia.**

**Tell your doctor if you need to have any dental treatment or dental surgery.**

A dental condition called jaw osteonecrosis has been reported in some patients being treated with Aredia or with other drugs in the same class as Aredia. You may need to have dental treatments completed before starting it.

Your doctor may want to take special precautions if you have any of the above conditions.

### ***Taking other medicines***

**Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.**

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

- \* medicines that may have side effects on your kidneys
- \* thalidomide, a medicine used to treat multiple myeloma
- \* other bisphosphonate medicines
- \* calcitonin

You may need to take different amounts of your medicines or you may need to take different medicines. Your doctor and pharmacist have more information.

**If you have not told your doctor about any of these things, tell him/her before you have Aredia.**

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## **How Aredia is given**

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### ***How it will be given***

Aredia will be given by slow intravenous infusion into a vein. The dry powder in the vial is dissolved in sterile water and then put into an intravenous drip. An infusion may last several hours, depending on the dose given and whether or not you have kidney problems.

You may also be given an infusion of fluids to ensure that you do not become dehydrated.

### ***How much you need***

The dose is usually between 30 mg and 90 mg, depending on the condition being treated.

The need for more doses will depend on how well your body responds to the treatment. Your doctor will decide how many infusions you need, how often you should receive them. If you have cancer in the bone you will usually receive a dose every 4 weeks. But if you are having chemotherapy every 3 weeks, Aredia can be given at the same time.

Your doctor may also prescribe a daily calcium supplement and a multiple vitamin containing Vitamin D.

Since bisphosphonate medicines may cause damage to the kidneys, you will have a blood test before each dose to make sure this medicine is not affecting your kidneys.

### ***If you have too much***

**Tell your doctor if you have any of the following symptoms. They may mean that the level of calcium in your blood has fallen too far.**

- \* unusual lightheadedness, dizziness or faintness
- \* numbness or tingling sensation
- \* muscle cramps

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## **While you are having Aredia**

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### ***Things you must do***

**Follow your doctor's instructions carefully and keep all appointments.**

You will need regular blood tests to make sure the treatment is working. In the early stages of treatment for high blood calcium, these tests may be done several times a day.

Regular blood tests can also find side effects before they become serious.

**Tell your doctor immediately if you become pregnant while having treatment with Aredia.**

Your doctor can discuss with you the risks of having it while you are pregnant.

**Tell your doctor and dentist immediately about any dental symptoms including pain or unusual feeling in your teeth or gums, or any dental infections.**

**A dental condition called jaw osteonecrosis has been reported in some patients being treated with Aredia or with other drugs in the same class as Aredia. Tell your dentist that you are being treated with Aredia.**

Your dentist may need to take special precautions.

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are having Aredia.**

**Tell any other doctor, dentist or pharmacist who treats you that you are having Aredia.**

### ***Things you must not do***

**Do not give this medicine to anyone else even if their symptoms seem to be the same as yours.**

**Do not use it to treat any other complaints unless your doctor tells you to.**

## **Things to be careful of**

**Be careful driving, operating machinery or doing jobs that require you to be alert after you have a dose of Aredia until you know how it affects you. If you are returning home immediately after the infusion, arrange to have someone else drive.**

This medicine may cause dizziness or sleepiness in some people, especially right after the infusion. It usually does not last longer than 24 hours.

**Practice good dental hygiene. Your routine dental hygiene should include:**

- \* brushing your teeth and tongue after every meal and at bedtime
- \* gentle flossing once a day to remove plaque
- \* keeping your mouth moist by drinking water (many cancer medicines can cause "dry mouth" which can lead to decay and other dental problems)
- \* avoiding use of mouthwash that contains alcohol.

**Use a mirror to check your teeth and gums regularly for any changes such as sores or bleeding gums. If you notice any problems, tell your doctor or dentist immediately.**

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are having Aredia.**

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. If you are over 65 and you have a serious heart or kidney problem, you may be more likely to have unwanted effects from your treatment.

**Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer**

**any questions you may have.**

**Tell your doctor if you notice any of the following side effects and they worry you:**

- \* short-lasting fever and flu-like symptoms, sometimes with chills, tiredness and general discomfort
- \* pain, redness and swelling at the site of the infusion
- \* short-lasting pain in bones, joints or muscles
- \* generalised pain
- \* muscle cramps
- \* indigestion, loss of appetite, feeling sick or vomiting
- \* constipation or diarrhoea
- \* headache
- \* dizziness or lightheadedness
- \* sleepiness or tiredness
- \* feeling agitated or being unable to sleep
- \* irritated eyes, blurred vision, eye pain, sensitivity to light, objects appearing yellow

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:**

- \* signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; shortness of breath, wheezing or troubled breathing
- \* constant "flu-like" symptoms (chills, fever, sore throat, aching joints, sores in mouth, swollen glands, tiredness or lack of energy, unusual bleeding or bruising) that could be a sign of blood problems
- \* numbness, tingling or severe muscle cramps
- \* swelling of ankles, feet or lower legs
- \* fainting spells or seizures (fits)
- \* confusion or hallucinations (seeing, hearing or feeling things that are not there)
- \* decrease in amount of urine or bloody urine

- \* pain in the mouth, teeth or jaw, swelling or sores inside the mouth, numbness or a "heavy jaw feeling" or loosening of a tooth. These symptoms could be a sign of a jaw-bone problem known as jaw osteonecrosis.

The above side effects may be serious. You may need urgent medical attention.

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

Some people may have other side effects not yet known or mentioned in this leaflet. Some side effects can only be found by laboratory testing.

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## **After having Aredia**

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### **Storage**

**If you are keeping a supply of Aredia at home:**

- \* Store the medicine in a cool dry place at room temperature.
- \* Do not store Aredia or any other medicine in the bathroom or near a sink.
- \* Do not leave it in the car or on window sills.

**Keep the medicine where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### **Disposal**

**If you no longer need Aredia or it has passed its expiry date, return any unused medicine to your pharmacist.**

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## **Product description**

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### ***What it looks like***

Aredia is packaged in glass vials containing the active ingredient, disodium pamidronate, in a dry powder form. An ampoule containing water for injections is provided for use in dissolving the powder.

### ***Ingredients***

Aredia vials are available in three sizes, containing 15 mg, 30 mg or 90 mg disodium pamidronate. The vials also contain mannitol and phosphoric acid.

### ***Sponsor***

Aredia is supplied in Australia by:  
Novartis Pharmaceuticals Australia  
Pty Limited  
ABN 18 004 244 160  
54 Waterloo Road  
North Ryde NSW 2113  
Telephone 1 800 671 203

Web site: [www.novartis.com.au](http://www.novartis.com.au)

(R) = Registered Trademark

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30 mg vial AUST R 53889

90 mg vial AUST R 53891