What is in this leaflet

Please read this leaflet carefully before you start using Pamidronate BNM.

This leaflet answers some common questions about Pamidronate BNM. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from www.medsafe.govt.nz.

Reading this leaflet 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 using Pamidronate BNM against the benefits this medicine is expected to have for you.

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

**Keep this leaflet with the medicine.**

You may want to read it again.

What Pamidronate BNM is used for

Pamidronate BNM contains disodium pamidronate, which belongs to a group of medicines called bisphosphonates. It works by slowing down the rate of bone change and helps restore the amount of calcium in the blood to normal.

Pamidronate BNM is used in 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.

Pamidronate BNM can also be used when the amount of calcium in the blood 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.

Your doctor may have prescribed this medicine for another reason. **Ask your doctor if you have any questions about why it has been prescribed for you.**
Pamidronate BNM is available only with a doctor's prescription.

Pamidronate BNM is not addictive.

**Before you are given Pamidronate BNM**

Pamidronate BNM is not suitable for everyone.

**When you must not be given it**

Do not use Pamidronate BNM if you are allergic to any medicine containing bisphosphonates or any of the ingredients listed at the end of this leaflet. Other bisphosphonate medicines can cause breathing difficulties in people with asthma who are allergic to aspirin.

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

Do not use it after the expiry date (‘EXP’ on vial) printed on the pack. If you use it after the expiry date has passed, it may not work as well.

Do not use it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using this medicine, talk to your doctor.

**Before you are given it**

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- 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)
- 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 Pamidronate BNM.
Tell your dentist you may be receiving Pamidronate BNM.
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 Pamidronate BNM or with other drugs in the same class as Pamidronate BNM. 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.

Do not give Pamidronate BNM to a child aged 5 years and under.
There is not enough information to recommend the use of this medicine for children under 5 years old.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using Pamidronate BNM.

**Taking other medicines**

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

Tell any health professional who is prescribing a new medicine for you that you are using Pamidronate BNM.

Some medicines and Pamidronate BNM 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.

The above medicines may be affected by Pamidronate BNM, or may affect how well it works. You may need different amounts of Pamidronate BNM, or use it at different times, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using Pamidronate BNM.

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**How Pamidronate BNM is given**

Read the label carefully and follow all directions given to you by your doctor and pharmacist.
They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

**How it will be given**
Pamidronate BNM will be given by slow intravenous infusion into a vein. 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 so that you do not become dehydrated.

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.

**How much is given**

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, and how often you should receive them.

Ask your doctor or pharmacist if you are unsure of the correct dose for you. This depends on your condition and whether or not you are taking any other medicines.

If you receive the wrong dose, Pamidronate BNM may not work as well and your problem may not improve.

**How long you will be given it**

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, Pamidronate BNM can be given at the same time.

If you have Paget’s disease, you will normally get a single infusion and a repeat treatment depending on whether you need it.

If you have high calcium levels in the blood, you will get a single dose, or divided into 2–3 consecutive daily doses. You may receive a repeat treatment depending on whether you need it.

If you are unsure whether you should stop using Pamidronate BNM, talk to your doctor or pharmacist.

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**While you are being given Pamidronate BNM**

**Things you must do**

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using Pamidronate BNM. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are using this medicine.
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 Pamidronate BNM or with other drugs in the same class as Pamidronate BNM.

Tell your doctor immediately if you become pregnant while having treatment with Pamidronate BNM. Your doctor can discuss with you the risks of having it while you are pregnant.

Keep all of your doctor's appointments so that your progress can be checked. 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.

See your doctor if you feel that your condition is not improving or is getting worse.

**Things you must not do**

Do not give your medicine to anyone else, even if they have the same condition as you. This medicine is only intended for the use of the patient it has been prescribed for.

Do not use Pamidronate BNM 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 Pamidronate BNM 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.

**Things that may help with your condition**

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.
In case of overdose

If you are given too much

Tell your doctor if you have any of the following symptoms:
- unusual light-headedness, dizziness or faintness
- numbness or tingling sensation
- muscle cramps.

They may mean that the level of calcium in your blood has fallen too far.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Pamidronate BNM.
Like all medicines, Pamidronate BNM may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following 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 light-headedness
- sleepiness or tiredness
- feeling agitated or being unable to sleep
- irritated eyes, blurred vision, eye pain, sensitivity to light, objects appearing yellow
- irregular heart rhythm (atrial fibrillation).

Unusual fracture of the thigh bone particularly in patients on long-term treatment for osteoporosis may occur rarely. Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin as this may be an early indication of a possible fracture of the thigh bone.
Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- serious allergic reaction (rash, itching or hives on the skin; swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, shortness of breath)
- 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.

These are very serious side effects; you may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.
Other side effects not listed above may also occur in some patients. Some side effects can only be found by laboratory testing.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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**After using Pamidronate BNM**

**Storage**

If you are keeping a supply of Pamidronate BNM at home:

Keep Pamidronate BNM in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window sill.
Do not leave it in the car.
Heat and damp can destroy some medicines.

Keep it and any other medicine where children cannot reach it.
A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not keep Pamidronate BNM past its expiry date.
Disposal

Return any unused medicine, and any medicine past its expiry date (as shown on the dispensing label or on the packaging) to your pharmacy.

Product description

What it looks like

Pamidronate BNM is available as individually packed vials of 5 mL or 10 mL in size, containing 15 mg, 30 mg, 60 mg or 90 mg disodium pamidronate. The solution is clear and colourless.

Ingredients

Active ingredient:
- disodium pamidronate

Inactive ingredients:
- mannitol
- phosphoric acid
- sodium hydroxide
- water for injections

Pamidronate BNM does not contain lactose, sucrose, tartrazine or any other azo dyes. Pamidronate BNM does not contain any preservatives.

Sponsor details

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