

PATIENT INFORMATION ON BISPHOSPHONATES (TABLETS)

Examples of brand names: for **Alendronate** - Adronat, Alendrobell, Densaste, Dronalen, Fonať, Fosamax, Fosamax Plus, Fosamax D, Ossmax, ReddyMax
for **Risedronate** – Acris Once-a-Week, Actonel, Actonel Combi, Actonel Combi D, Actonel EC, Actonel Once-a-Month, Atelvia Once-a-Month

This information sheet has been produced by the Australian Rheumatology Association to help you understand the medicine that has been prescribed for you. It includes important information about:

- **how you should take your medicine**
- **what are the possible side effects**
- **what tests you must have to monitor your condition and to detect unwanted effects**
- **other precautions you should take when you are taking drug name**

Please read it carefully and discuss it with your doctor.

IMPORTANT THINGS TO REMEMBER

- While taking bisphosphonates you should see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects.
- If you are concerned about any side effects, you should contact your rheumatologist as soon as possible.

For more information about OSTEOPOROSIS see the Healthy Bones Australia website healthybonesaustralia.org.au or phone Healthy Bones Australia on 1800 242 141.

What are bisphosphonates?

Bisphosphonates are medicines used to treat bone diseases such as osteoporosis and Paget's disease. Alendronate and risedronate are the most commonly prescribed bisphosphonate tablets in Australia.

Osteoporosis is a common disease of reduced bone mass leading to fragile and brittle bones that may break (fracture) more easily, even as a result of normal activity (as distinct from a fall). Fractures may be painful and restrict a person's ability to carry out their normal daily tasks.

In osteoporosis, bisphosphonates reduce the risk of a broken bone or fracture.

In Paget's disease, the formation of abnormal bone causes deformity and pain. Bisphosphonate medicines can help this.

How do they work?

Bone undergoes constant turnover with old bone breaking down and new bone being formed to take its place. This usually happens in a balanced way. If the cycle becomes unbalanced, bone is broken down faster than it is replaced. This leads to osteoporosis.

Bisphosphonates slow or stop the bone breaking down. As a result, bone density may increase over time so the risk of fractures is reduced.

What benefit can you expect from your treatment?

Since osteoporosis doesn't usually have any symptoms such as pain (until a fracture occurs) you will not 'feel' any immediate benefit from your treatment with bisphosphonates.

If used for Paget's disease, bone pain may lessen with time. Your doctor will explain the likely benefits relevant to you.

You may be asked to have tests to check the effect of treatment on your bones. For example, a bone mineral density test (DEXA scan) is usually done after one to two years of treatment. This is a type of x-ray, which involves a very small amount of radiation.

Tests of urine or blood are sometimes used to measure the effects of treatment on bone formation and breakdown.

How are bisphosphonates taken?

Bisphosphonates come as tablets, but can also be given by injection (see separate information sheet).

It is important to follow the directions carefully to avoid side effects and to make sure the tablets work properly. Tablets should be taken swallowed whole with a glass of water and you

should remain in an upright position ie, do not lie down immediately after swallowing the tablet. See Important things to remember on the first page of this sheet and ask your doctor about the instructions relevant to the medication you have been provided.

What is the dosage?

Tablets come in different strengths. The dose will depend on the type of bisphosphonate being taken and the condition for which it is being used.

For osteoporosis, the medicines are taken as a single tablet once a week or once a month for a number of years.

For Paget's disease they are usually taken daily for a limited period. Always follow the instructions provided in the packaging unless otherwise directed by a doctor.

Are other medicines taken with bisphosphonates?

It is safe to use most other medicines when you are taking bisphosphonates (see Precautions on page 3). However, bisphosphonates should not be taken with some other osteoporosis medicines (see Precautions on page 3)

It is also important not to take other medicines within 30 minutes of taking bisphosphonate tablets.

Your doctor may usually recommend you to take calcium and vitamin D supplements as well as your bisphosphonate. Some bisphosphonates are packaged in combination with Vitamin D or calcium.

How long is the treatment continued?

For osteoporosis, treatment with bisphosphonates is usually given for five years if the fracture risk is no longer high but continued up to an additional five years if the fracture risk remains high. Your doctor will review your progress each year.

For Paget's disease, the treatment may be given for a shorter period of time.

Are there any side effects?

Most people who take bisphosphonate tablets do not experience side effects. Tell your doctor if you are concerned about possible side effects. A reduction in dose or change to another medicine may minimise the side effects so that you can continue to have treatment for your bones.

Most common possible side effects

- Bisphosphonate tablets may cause *inflammation of the oesophagus or stomach* resulting in stomach pain, heartburn, feeling sick (nausea), vomiting, constipation or diarrhoea.
- *Headache and/or dizziness* may occur.
- *Mouth ulcers, aching muscles, joints and/or bones and swelling of joints* may also occur but do not last for long.

Less common or rare possible side effects

- A potentially serious but very rare side effect with bisphosphonates is *osteonecrosis of the jaw (ONJ)* which can occur on the order of 1/10,000 to 1/100,000 patients per year. This condition presents with jaw pain. It usually occurs after dental work which does not heal properly. For most patients who are taking oral bisphosphonates, the benefits of these medicines outweigh the potential risk of ONJ. As a precaution, it is recommended that any dental infections should be treated and any planned extractions be performed before starting bisphosphonate treatment.
- Bisphosphonates can cause *skin reactions* such as rash or redness of the skin, which is sometimes made worse by sunlight. They can also cause *itchiness*.
- *Blurred vision, pain or redness* in the eye (called iritis) may occur and may need to be treated with eye drops. If this occurs, see your doctor.
- Fractures affecting the upper thigh bone have been reported. The risk is increased with longer time period of taking these drugs, the use of steroids and having diabetes.
- There is a small but possible increase in the risk of cancer of the oesophagus or gullet in taking this medication for more than 5 years. For most people the benefit of taking this medication outweighs the possible risk.

What precautions are necessary?

Care of your teeth and mouth

- Before starting bisphosphonate treatment, have your teeth checked by your dentist. If surgery on the jawbone is necessary, this should be done before you start the treatment.
- While taking a bisphosphonate, maintain good oral hygiene and have regular dental check-ups.

Blood tests

- Monitoring blood tests are not usually required for people taking bisphosphonates for osteoporosis, although in certain situations these may be needed.
- In Paget's disease, your doctor may ask you to have a blood test to measure bone turnover and response to treatment.

Use with other medicines

- It is important not to take other medicines within 30 minutes of taking bisphosphonate tablets.
- You should tell your doctor (including your general practitioner, rheumatologist and others) about all medicines you are taking or plan to take. This includes over the counter or herbal/naturopathic medicines. You should also mention your treatment when you see other health professionals.
- Bisphosphonates should not be taken with other osteoporosis medicines such as denosumab (Prolia), raloxifene (Evista), teriparatide (Forteo) or romosozumab (Evenity).
- The risk of side effects from the low doses of aspirin used to prevent heart attack and strokes is not increased when taken with bisphosphonates.
- Nonsteroidal anti-inflammatories (NSAIDs) may also cause inflammation of the oesophagus and stomach so your doctor may advise you not to take NSAIDs if you are taking a bisphosphonate.
- Methotrexate can be taken safely with bisphosphonates.
- The simple pain reliever paracetamol and combined medicines such as Panadeine and Panadeine Forte can be used while taking bisphosphonates provided you take them as directed.
- The absorption of bisphosphonates from the stomach can be reduced by over-the-counter antacids such as Gaviscon, Mylanta and Rennie and by prescribed medicines such as omeprazole (Acimax/Losec) or esomeprazole (Nexium).

Use with alcohol

- Because these medicines can increase your risk of stomach inflammation, you should avoid heavy alcohol use while taking them. Drinking more than 4 standard drinks on one occasion, even if infrequently, is strongly discouraged.

Use in pregnancy and breastfeeding

- Bisphosphonates are not recommended to be taken during pregnancy or when breastfeeding. If you are planning a family or become pregnant you should discuss this with your doctor as soon as possible.
- More detailed information is available at https://rheumatology.org.au/Portals/2/Documents/Public/Professionals/210914_Pregnancy_Prescribing_Info_FINAL.pdf?ver=2022-07-07-093013-573

How to store bisphosphonates?

- Store bisphosphonate tablets in a cool, dry place, away from direct heat and light.
- Keep all medicines out of reach of children.

Questions?

If you have any questions or concerns write them down and discuss them with your doctor.

Your doctor's contact details

You should see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects.

This Information Sheet has been prepared using materials obtained from various sources which have been reviewed by the Australian Rheumatology Association (ARA). It contains general information only and does not contain a complete or definitive statement of all possible uses, actions, precautions, side effects or interactions of the medicines referenced. This information is not intended as medical advice for individual conditions nor for making an individual assessment of the risks and benefits of taking a particular medicine. Decisions regarding the assessment and treatment of patients are the sole responsibility of the treating medical professional, exercising their own clinical judgment and taking into account all of the circumstances and the medical history of the individual patient.

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