

Package leaflet: Information for the patient

Osteral 35 mg, Film-Coated Tablets

Risedronate sodium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, consult your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

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2. What you need to know before you take Osteral
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1. What Osteral is and what it is used for

This medicine belongs to a group of non-hormonal medicines called bisphosphonates which are used to treat bone diseases. It works directly on your bones to make them stronger and therefore less likely to break.

Bone is a living tissue. Old bone is constantly removed from your skeleton and replaced with new bone.

Postmenopausal osteoporosis is a condition occurring in women after the menopause where the bones become weaker, more fragile and more likely to break after a fall or strain.

Osteoporosis can also occur in men due to a number of causes including aging and/or a low level of the male hormone, testosterone.

The spine, hip and wrist are the most likely bones to break, although this can happen to any bone in your body. Osteoporosis related fractures can also cause back pain, height loss and a curved back. Many patients with osteoporosis have no symptoms and you may not even have known that you had it.

This medicine is used for:

- The treatment of osteoporosis in men.
- The prevention and treatment of osteoporosis in postmenopausal women even if osteoporosis is severe.

It reduces the risk of spinal and hip fracture.

2. What you need to know before you take Osteral

Do not take Osteral:

- if you are allergic (hypersensitive) to risedronate sodium or to any of the ingredients of this medicine (listed in section 6).
- if your doctor told you that you have low blood calcium level (hypocalcemia).
- if you may be pregnant, are pregnant or are planning to become pregnant.
- if you are breast-feeding.
- if you have severe kidney problems.

Warnings and precautions:

Consult your doctor or pharmacist before taking Osteral:

- if you are unable to stay in an upright position (sitting or standing) for at least 30 minutes.
- if you have abnormal bone and mineral metabolism (for example lack of vitamin D or parathyroid hormone abnormalities both leading to a low blood calcium level).
- if you have had problems in the past with your oesophagus (the tube that connects your mouth with your stomach). For instance you may have had pain or difficulty in swallowing food or you have previously been told that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus)
- if you have been told by your doctor that you have an intolerance to some sugars (such as lactose).
- if you have had or have pain, swelling or numbness of the jaw or a "heavy jaw feeling" or loosening of a tooth.
- if you are under dental treatment or will undergo dental surgery, tell your dentist that you are being treated with this medicine.

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.

Children and adolescents:

This medicine is not recommended for use in children below 18 years of age due to insufficient data on safety and efficacy.

Other medicines and Osteral:

Consult your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Medicines containing one of the following lessen the effect of this medicine if taken at the same time:

- Calcium
- Magnesium
- Aluminium (for example some indigestion mixtures)
- Iron

Take these medicines at least 30 minutes after you take Osteral.

Osteral with food, drinks and alcohol:

It is very important that you do NOT take your medicine with food or drinks (other than plain water) so that it can work properly. In particular do not take this medicine at the same time as dairy products (such as milk) as they contain calcium (see section 2 "Other medicines and Osteral").

Take food and drinks (other than plain water) at least 30 minutes after Osteral.

Pregnancy and breast-feeding:

Do not take this medicine if you may be pregnant, are pregnant or are planning to become pregnant. The potential risk associated with the use of risedronate sodium in pregnant women is unknown.

Do not take this medicine if you are breast-feeding.

This medicine should only be used to treat non and postmenopausal women.

Driving and using machines:

This medicine is not known to affect your ability to drive and use machines.

Important information about some of the ingredients of Osteral:

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking this medicinal product.

3. How to take Osteral

Always take this medicine exactly as your doctor has told you. Consult your doctor or pharmacist if you are not sure.

Taking this medicine:

- The usual dose is one tablet, once a week.
- Choose one day of the week that best fits your schedule. Every week, take your tablet on your chosen day.
- Take your tablet at least 30 minutes before the first food, drink (other than plain water) or other medicine of the day.
- Take your tablet while you are in an upright position (you may sit or stand) to avoid heartburn.
- Swallow it with at least one glass (120 ml) of plain water.
- Swallow it whole. Do not suck or chew the tablet.
- Do not lie down for 30 minutes after taking the tablet.
- Your doctor will tell you if you need calcium and vitamin supplements, if you are not taking enough from your diet.

If you take more Osteral than you should

If you or somebody else has accidentally taken more of this medicine than prescribed, drink one full glass of milk and seek medical attention.

If you forget to take Osteral

If you have forgotten to take your tablet on your chosen day, take it on the day you remember. Return to taking one tablet once a week on the day the tablet is normally taken. Do not take two tablets in one day to make up for the tablet you missed.

If you stop taking Osteral

If you stop treatment you may begin to lose bone mass. Please consult your doctor before you consider stopping treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking this medicine and contact a doctor immediately if you experience any of the following:

- Symptoms of a severe allergic reaction such as: swelling of the face, tongue or throat; difficulties in swallowing; hives and difficulties in breathing.
 - Severe skin reactions that can include blistering of the skin.
- Tell your doctor promptly if you experience the following side effects:
- Eye inflammation, usually with pain; redness and light sensitivity.
 - Bone necrosis of the jaw (osteonecrosis) associated with delayed healing and infection, often following tooth extraction.
 - Symptoms from oesophagus such as pain when you swallow, difficulties in swallowing, chest pain or new/worsened heartburn.

Common side effects (may affect up to 1 in 10 people):

Indigestion; feeling sick; stomach ache; stomach cramps or discomfort; constipation; feelings of fullness; bloating; diarrhoea; pain in your bones, muscles or joints; headache.

Uncommon side effects (may affect up to 1 in 100 people):

Inflammation or ulcer of the oesophagus causing difficulty and pain in swallowing; inflammation of the stomach and duodenum (bowel draining the stomach); inflammation of the coloured part of the eye (iris) (red painful eyes with a possible change in vision).

Rare side effects (may affect up to 1 in 1000 people):

Inflammation of the tongue (red swollen, possibly painful), narrowing of the oesophagus; abnormal liver blood tests; blood calcium and phosphate levels may fall in the beginning of treatment. These changes are usually small and cause no symptoms.

During post-marketing experience, the following have been reported:

- Very rare: talk to your doctor if you have ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear.
- unknown frequency: hair loss; liver disorders, some cases were severe.

Reporting side effects

If you get any side effects, consult your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Osteral

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and the outer packaging. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Osteral contains

- The active substance is risedronate sodium.

Each film-coated tablet contains 35 mg of risedronate sodium.

- The other ingredients are lactose, magnesium stearate, microcrystalline cellulose, crospovidone, titanium dioxide, talc, simethicone, polyvinyl alcohol-polyethylene glycol copolymer and triethyl citrate.

What Osteral looks like and contents of the pack

White round film-coated tablets

Osteral 35 mg is available in boxes containing 4 tablets.

Marketing Authorisation Holder and Manufacturer

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Reg. N° Lebanon: 219727/09

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- Do not do yourself the pharmacist is experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- keep all medicaments out of reach of children.