**Package leaflet: Information for the user**

**Atronate 35 Once a week**
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 symptoms are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4

**What is in this leaflet?**


## 1. What Atronate 35 Once a week is and what it is used for

Atronate 35 Once a week 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 ageing 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.

**What Atronate 35 Once a week is used for**
Treatment osteoporosis in postmenopausal women, even if osteoporosis is severe. It reduces the risk of spinal and hip fractures.
Treatment of osteporosis in men w of ith high risk of fractures.

## 2. What you need to know before you take Atronate 35 Once a week

**Do not take Atronate 35 Once a wee**k

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

**Warnings and precautions**

Talk to your doctor or pharmacist, or nurse before taking Atronate 35 Once a week

- if you are unable to stay or stand upright position (sitting or standing) for at least 30 minutes.
- if you have abnormal bone or mineral metabolism (for example lack of vitamin D, parathyroid hormone abnormalities both leading to a low blood calcium level).
- If you have or have had problems in the past with your oesophagus (the tube that connects your mouth with your stomach). For instance you may have or 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

Your doctor will advise you on what to do when taking Atronate 35 "Once a week if you have any of the above.

Children and adolescents risedronate sodium is not recommended for use in children below 18 due to insufficient data on safety and efficacy.

**Other medicines and Atronate 35 Once a week**

Medicines containing one of the following lessen the effect of of Atronate 35 Once a week if they are taken at the same time:

- calcium
- magnesium
- aluminium(for example some indigestion mixtures)
- iron

Take these medicines at least 30 minutes after your Atronate 35 Once a week.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines

**Atronate 35 Once a week with food and drink**
It is very important that you do NOT take your Atronate 35 Once a week tablet with food or drinks (other than water). It is especially important that this medicinal product is not taken at the same time as dairy produce (such as milk) because they contain calcium (see section 2 ““Other medicines and Atronate 35 Once a week ”).
Take food and drinks (other than plain water) at least 30 minutes after taking Atronate 35 “Once a week.

**Pregnancy and breast-feeding**
Do not take Atronate 35 Once a week if you may be pregnant or are plannig to become pregnant (see section 2 “Do not take Atronate 35 Once a week). The potential risk associated with the use of risedronate sodium (active substance in Atronate 35 Once a week) in pregnant women is unknown
Do not take Atronate 35 Once a week if you are breast feeding (see section 2 “Do not take Atronate 35 Once a week).

Atronate 35 Once a week should only be used to treat postmenopausal women and men.

**Driving and using machines**
Atronate 35 Once a week is not known to affect your ability to drive or use machines.

**Atronate 35 Once a week contains a small amount of lactose (see section 2, “Warnings and precautions”).**

## 2. How to use Atronate 35 Once a week

Always take Atronate 35 Once a week exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one Atronate 35 Once a week (35 mg risedronate sodium) once a week.
Choose one day of the week that best fits your schedule. Take one Every week, take the Atronate 35 Once a week tablet on your chosen day.

For your convenience, so that you take your tablet on the right day every week, there is a feature included with the Atronate 35 Once a week pack:

There are boxes/spaces on the back of the blister card. Please mark the day of the week you have chosen to take your Atronate 35 Once a week. Also write in the dates you will take the tablet.

**When to take your Atronate 35 Once a week:**
Take your Atronate 35 Once a week at least 30 minutes before the first food, drink (other than plain water) or other medicine of the day.

## 3. How to take your Atronate 35 Once a week:

- Take the tablet whilst you are in an upright position (you may sit or stand) to avoid heartburn Swallow it with at least a 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 your tablet.

Your doctor will tell you if you need to take extra calcium and vitamin supplements, if you do not get enough from your daily diet.

**If you take more Atronate 35 Once a week than you should**
If you or somebody else has accidentally taken more Atronate 35 Once a week tablets than prescribed, drink a full glass of milk and seek medical attention.

**If you forget to take Atronate 35 Once a week**
Do not take two tablets on one day to make up for the tablet you missed.

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.

**If you stop taking Atronate 35 Once a week**
If you stop treatment you may begin to lose bone mass. Please talk to 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 Atronate 35 Once a week and contact a doctor immediately** if you experience any of the following:
• Symptoms of a severe allergic reaction such as:
• Swelling of 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 (see section 2, "Warnings and precautions").
• Symptoms from oesophagus such as pain when you swallow, difficulties in swallowing, chest pain or new or worsened heartburn. 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.

However in clinical studies the other side effects that were observed were usually mild and did not cause the patient to stop taking their tablets.
**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 (the tube that connects your mouth with your stomach) causing difficulty and pain in swallowing (see also section 2, "Warnings and precautions"), 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 1,000 people)
• Inflammation of the tongue (red swollen, possibly painful), narrowing of the oesophagus (the tube that connects your mouth with your stomach)
. • Abnormal liver tests have been reported. These can only be diagnosed from a blood test.

**Very rare** (may affect up to 1 in 10,000 people)
• 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.

During post-marketing experience, the following have been reported (unknown frequency):
• Hair loss
• Liver disorders, some cases were severe.

Rarely, at the beginning of treatment, a patient's blood calcium and phosphate levels may fall. These changes are usually small and cause no symptoms.

**Reporting of side effects**
If you get any side effects, talk to your doctor or , pharmacist or nurse . This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
Pharmaceutical Services
Ministry of Health

CY-1475,
www.moh.phs.gov.cy/phs , Fax: + 357 22608649

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Atronate 35 Once a week

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP.. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. . These measures will help to protect the environment.

## 6. Contents of the pack and other information

### What Atronate 35 Once a week contains

- The active substance is risedronate sodium. Each tablet contains 40.17 mg risedronate sodium hemypentihydrate equivalent to risedronate sodium 35mg.
- The other ingredients are:
  Tablet core: Starch pregelatinized (Starch maize 1500), Microcrystalline Cellulose; Cross povidone; Magnesium stearate.
  Film coating: Hypromellose, Lactose monohydrate, Titanium dioxide (E171), Macrogol 4000.

### What Atronate 35 Once a week looks like and contents of the pack

Atronate 35 Once a week are white round biconvex film-coated tablets. It is supplied in blister packs of 1, 2, 4, 8, 12 and 16 film-coated tablets.

Not all packsizes may be marketed.

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**This medicinal product is authorised in the Member States of the EEA under the following names:**

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