



MADRONATE[®]

Risedronate sodium 35 mg

Film-coated tablets

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Madronate is and what it is used for

What Madronate is

Madronate 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 Madronate is used for

The treatment of osteoporosis

- In postmenopausal women, even if osteoporosis is severe. It reduces the risk of spinal and hip fractures.
- In men.

2. Before you take Madronate

Do not take Madronate

- If you are allergic to risedronate sodium or any of the other ingredients of **Madronate** (see section 6, "What **Madronate** contains")
- If your doctor has told you that you have a condition called hypocalcaemia (a low blood calcium level)
- If you may be pregnant, are pregnant or planning to become pregnant
- If you are breast-feeding
- If you have severe kidney problems.

Take special care with Madronate

- 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, 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.
- If you have been told by your doctor that you have 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 **Madronate**.

Your doctor will advise you on what to do when taking **Madronate** if you have any of the above.

Children

Risedronate sodium is not recommended for use in children below age 18 due to insufficient data on safety and efficacy.

Taking other medicines

Medicines containing one of the following lessen the effect of **Madronate** if taken at the same time:

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

Take these medicines at least 30 minutes after your **Madronate** tablet.

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

Food and drink

It is very important that you do not take your **Madronate** tablet with food or drinks (other than 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, "Taking other medicines").

Take food and drinks (other than water) at least 30 minutes after your **Madronate** tablet.

Pregnancy and breast-feeding

Do not take **Madronate** if you may be pregnant, are pregnant or planning to become pregnant (see section 2, "Do not take **Madronate**"). The potential risk associated with the use of risedronate sodium (active substance in **Madronate**) in pregnant women is unknown.

Do not take **Madronate** if you are breast-feeding (See section 2, "Do not take **Madronate**").

Madronate should only be used to treat postmenopausal women and men.

Driving and using machines

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

Important information about some of the ingredients of Madronate

Madronate contains a small amount of lactose (See section 2, "Take special care with **Madronate**").

3. How to take Madronate

Dosage

Always take **Madronate** exactly as your doctor has told you. You should check with your doctor if you are not sure.

Usual dose:

Take one **Madronate** tablet (35 mg of risedronate sodium) once a week.

Choose one day of the week that best fits your schedule. Every week, take the **Madronate** tablet on your chosen day.

When to take the Madronate tablet

Take your **Madronate** tablet at least 30 minutes before the first food, drink (other than water) or other medicine of the day.

How to take the Madronate tablet

- Take the tablet whilst you are in an upright position (you may sit or stand) to avoid heartburn.
- Swallow it with at least one glass (120 ml) of water.
- Swallow it whole. Do not suck or chew it.
- Do not lie down for 30 minutes after taking your 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 Madronate than you should

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

If you forget to take Madronate

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 Madronate

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

4. Possible side effects

Like all medicines, **Madronate** can cause side effects, although not everybody gets them.

Stop taking Madronate 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, "Take special care with **Madronate**").
- 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 patients to stop taking their tablets.

Common side effects (less than 1 in 10 but more than 1 in 100 patients)

- 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 (less than 1 in 100 but more than 1 in 1000 patients)

- 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, "Take special care with **Madronate**"), inflammation of the stomach and duodenum (bowel draining the stomach).
- Inflammation of the colored part of the eye (iris) (red painful eyes with a possible change in vision).

Rare side effects (less than 1 in 1000 patients)

- 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.

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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Madronate

Keep all medicines out of reach of children.

Do not use **Madronate** after the expiry date which is stated on the carton.

The expiry date refers to the last day of that month.

Store below 30°C.

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

6. Further information

What Madronate contains

The active substance is risedronate sodium.

Each tablet contains 35 mg risedronate sodium, equivalent to 32.5 mg risedronic acid.

The other ingredients are:

Tablet core: lactose monohydrate, cellulose microcrystalline, crospovidone, magnesium stearate.

Film coating: yellow iron oxide (E172), red iron oxide (E172), hypromellose, hydroxypropyl-cellulose, silica colloidal anhydrous, titanium dioxide (E171), macrogol 400, macrogol 8000.

What Madronate looks like and contents of the pack

Madronate 35 mg film-coated tablets are biconvex, pale orange colored round tablet. The tablets are supplied in carton box containing one blister of 4 tablets.

Instructions



Pick a convenient day of the week.

Take your **Madronate** tablet on the same day every week.



Swallow one Tablet of **Madronate** whole the first thing in the morning with a cup of water.



Do not lie down, eat, drink or take other medications for 30 minutes.

Manufactured by: Zakład Farmaceutyczny Adamed Pharma S.A
Ksawerów, Poland

For: ARWAN Pharmaceutical Industries Lebanon s.a.l.
Jadra, Lebanon

THIS IS A MEDICAMENT

- 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.
- The doctor and the pharmacist are experts in medicines, their 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 the reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists