

PACKAGE LEAFLET: INFORMATION FOR THE USER
Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets , 35 mg
film-coated tablets
Risedronate sodium

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any questions, ask your doctor or 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.

In this leaflet:

1. What Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets is and what it is used for
2. Before you take Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets
3. How to take Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets
4. Possible side effects
5. How to store Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets
6. Further information

1. WHAT RISEDRONATE SODIUM ADAMED PHARMA ONCE A WEEK 35 MG FILM-COATED TABLETS IS AND WHAT IT IS USED FOR

Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets 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 Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets is used for

The treatment of osteoporosis in **postmenopausal women**, even if osteoporosis is severe. It reduces the risk of spinal and hip fractures.

Treatment of osteoporosis in men at high risk of fractures.

2. BEFORE YOU TAKE RISEDRONATE SODIUM ADAMED PHARMA ONCE A WEEK 35 MG FILM-COATED TABLETS

Do NOT take Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets

- If you are **allergic** (hypersensitive) to risedronate sodium or any of the other ingredients of Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets (see section 6, “What Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets 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 and talk to your doctor BEFORE you start taking Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets

- 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 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 [Name completed nationally]

Your doctor will advise you on what to do when taking Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets if you have any of the above.

Children and adolescents

Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets 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 Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets if taken at the same time

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

Take these medicines at least 30 minutes after your Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets tablet.

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

Taking Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets with food and drink

It is very important that you do NOT take your Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets tablet 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, "Taking other medicines").

Take food and drinks (other than plain water) at least 30 minutes after your Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets tablet.

Pregnancy and breast-feeding

Do NOT take Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets if you may be pregnant, are pregnant or planning to become pregnant (see section 2, "Do not take Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets "). The potential risk associated with the use of risedronate sodium (active substance in [Name completed nationally]) in pregnant women is unknown.

Do NOT take Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets if you are breast-feeding (see section 2, "Do not take [Name completed nationally])

Driving and using machines

Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets is not known to affect your ability to drive and use machines.

Important information about some of the ingredients of Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE RISEDRONATE SODIUM ADAMED PHARMA ONCE A WEEK 35 MG FILM-COATED TABLETS

Dosage

Always take Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets exactly as your doctor has told you. You should check with your doctor if you are not sure.

Usual dose:

Take ONE Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets tablet (35 mg of risedronate sodium) once a week.

Choose one day of the week that best fits your schedule. Every week, take the Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets 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 Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets pack:

There are boxes/spaces on the back of the cardboard carton. Please mark the day of the week you have chosen to take your Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets tablet. Also, write in the dates you will take the tablet.

WHEN to take the Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets tablet

Take your Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets tablet at least 30 minutes before the first food, drink (other than plain water) or other medicine of the day.

HOW to take the Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets 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 plain 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. Your diet should contain calcium and vitamin D (e.g. dairy products and fish).

If you take MORE Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets than you should

No specific information is available on the treatment of overdose with risedronate sodium. Decreases in serum calcium following substantial overdose may be expected. Signs and symptoms of hypocalcaemia may also occur in some of these patients.

If you or somebody else has accidentally taken more Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets than prescribed, drink one full **glass of milk** and **seek medical attention**.

If you FORGET to take Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets

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 a double dose to make up a forgotten tablet. If you have any further questions on the use of this product, ask your doctor.

If you STOP taking Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets

If you stop treatment you may begin to lose bone mass. Do not stop taking Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets without consultation with your doctor even if feel better. Your doctor will inform you about duration of treatment with [Name completed nationally].

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets can cause side effects, although not everybody gets them.

Stop taking Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets and contact a doctor immediately if you experience any of the following:

- Symptoms characteristics of severe tissue swelling (angioedema reaction)
 - Swelling of face, tongue or throat
 - Difficulties in swallowing
 - Hives and difficulties in breathing
- Severe skin reactions involving blisters under 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 and talk to your doctor before you start taking [Name completed nationally]”).
- Symptoms from oesophagus such as pain when you swallow, difficulties in swallowing, chest pain or new or worsened heartburn.

These reactions have been reported very rarely (less than 1 in 10,000 patients).

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 (1 to 10 users in 100)

- 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 (1 to 10 users in 1,000)

- 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 and talk to your doctor before you start taking [Name completed nationally]"), 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 (1 to 10 users in 10,000)

- 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 side effects

- 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.
- Hypersensitivity and skin reactions, including swelling of the face, mouth, tongue and/or neck (angioedema), skin rash and blistering, some severe life-threatening the skin and mucous membranes changes and inflammation of small blood vessels.

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.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL -Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE RISEDRONATE SODIUM ADAMED PHARMA ONCE A WEEK 35 MG FILM-COATED TABLETS

- Keep out of the reach and sight of children.
- Do not use this medicine after the expiry date which is stated on the pack.
- This medicinal product does not require any special storage conditions.

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 Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets 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, red iron oxide, hypromellose, hydroxypropylcellulose, silica, colloidal anhydrous, titanium dioxide, macrogol 400, macrogol 8000.

What Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets looks like and contents of the pack

Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets 35 mg film-coated tablets are biconvex, pale orange colored round tablet. The tablets are supplied in blister packs 2, 4 and 12 (3 x 4) tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Adamed Pharma S.A.

Pieńków, ul. M. Adamkiewicza 6A

05-152 Czosnów, Poland

Manufacturer:

Adamed Pharma S.A.

Pieńków, ul. M. Adamkiewicza 6A

05-152 Czosnów, Poland

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

{Poland} {Norifaz}

{Estonia} {Norifaz}

{Greece} {Bonmate}

{Lithuania} {Norifaz}

{Latvia} {Norifaz}

{Portugal} {Norifaz}

{Hungary} {Norifaz}

{Romania} {Lorine}

{Slovak Republic} {Norifaz 35 mg}

{France} {Risédronate Zentiva Lab 35 mg comprimé pelliculé}

{Ireland} {Risedronate sodium ADAMED PHARMA Once a week 35 mg film-coated tablets}

This leaflet was last approved in: