PACKAGE LEAFLET

Package leaflet: Information for the user

Risedronate Cipla 35 mg film-coated tablets (once weekly)

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, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is "Risedronate Cipla 35 mg film-coated tablets (once weekly)", but will be referred to as "Risedronate Cipla" throughout this leaflet.

What is in this leaflet

1. What Risedronate Cipla is and what it is used for

Risedronate Cipla contains the active substance risedronate sodium. It 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.

Risedronate Cipla is used for the treatment of osteoporosis in postmenopausal women, even if osteoporosis is severe. It reduces the risk of spinal and hip fractures. It is also used for the treatment of osteoporosis in men with high risk of fractures.

2. What you need to know before you take Risedronate Cipla

Do not take Risedronate Cipla

- 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, are pregnant or planning to become pregnant.
- if you are breast feeding.
- if you have severe kidney problems.

Warnings and precautions

Talk to your doctor or pharmacist before taking Risedronate Cipla

- 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 vitamin D deficiency, parathyroid hormone abnormalities) which can lead 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 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 Risedronate Cipla.

If any of the above situations apply to you, please talk to your doctor before you take this medicine.

Children and adolescents

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

Other medicines and Risedronate Cipla

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

Medicinal products which contain one or more of the below mentioned minerals reduce the effect of risedronate sodium if they are taken at the same time:

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

These medicines should be taken at least 30 minutes after taking Risedronate Cipla.

Risedronate Cipla may be used together with oestrogen supplementation (in women).

Risedronate Cipla with food and drink

It is very important that you do NOT take your Risedronate Cipla with food or drinks (other than plain water) so that it can work properly.

It is especially important that this medicine is not taken at the same time as dairy products (such as milk) as they contain calcium (see section 2 “Other medicines and Risedronate Cipla”).

Food and drinks (except water) should NOT be consumed for at least 30 minutes after taking Risedronate Cipla.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

Do not take Risedronate Cipla if you are breast-feeding (see section 2, “Do not take Risedronate Cipla”).

Risedronate Cipla should only be used to treat postmenopausal women and men.

Driving and using machines

Risedronate Cipla is not known to affect your ability to drive or use machines.

Risedronate Cipla contains lactose

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

3. How to take Risedronate Cipla

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

The recommended dose is one Risedronate Cipla (35 mg risedronate sodium) once a week. Choose one day of the week that best fits your schedule. Every week, take the Risedronate Cipla 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 Cipla pack:

There are boxes/spaces on the carton. Please mark the day of the week you have chosen to take your Risedronate Cipla. Also, write in the dates you will take the tablet.

When to take your Risedronate Cipla

Take your Risedronate Cipla at least 30 minutes before the first food, drink (other than plain water) or other medicine of the day.

How to take your Risedronate Cipla

- Take the tablet whilst you are in an upright position (you may sit or stand). This prevents heartburn (burning feeling in the throat).
- Swallow the tablet with at least one glass (120 ml) of plain water.
- Swallow the tablet 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.

Use in children and adolescents

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

If you take more Risedronate Cipla than you should

If you or somebody else has accidentally taken more Risedronate Cipla tablets than prescribed, drink a full glass of milk and seek medical attention. Overdose causes a decrease in the levels of calcium in your body, the symptoms of which include sudden, painful, involuntary contractions usually involving the muscles of the abdomen.

If you forget to take Risedronate Cipla

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 for a forgotten tablet.

If you stop taking Risedronate Cipla

Osteoporosis therapy is usually required for long periods. Please talk to your doctor before you consider stopping treatment. Stopping treatment will result in no beneficial effects of your therapy, and you may begin to loose bone strength again.

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 Risedronate Cipla and contact a doctor immediately if you experience any of the following:

- symptoms of a **severe allergic reaction** (angioedema) such as
  - swelling of face, lips, tongue, throat and/or neck
  - difficulties in swallowing
  - difficulties in breathing
  - hives, skin rash

- severe **skin reactions** such as
  - blistering of the skin, mouth, eyes and genitals (Stevens Johnson syndrome)
  - palpable red spots on the skin (leukocytoclastic vasculitis)
  - red rash over many parts of the body and/or loss of the outer layer of skin(toxic epidermal necrolysis)

Tell your doctor promptly if you experience the following side effects:

- Eye inflammation, inflammation of the coloured part of the eye (iris) (red painful eyes with possible change in vision) usually with pain, redness and light sensitivity.

- Bone necrosis of the jaw (osteonecrosis) a serve bone disease affecting the maxilla and the mandible, associated with delayed healing and infection, often following tooth extraction (see section 2, Warning and precautions").

- Inflammation or ulcer of the oesophagus with symptoms from oesophagus such as pain when you swallow, difficulties in swallowing, chest pain or new or worsened heartburn. Inflammation or ulcer of the stomach and the duodenum (bowel draining the stomach).

- 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):

- Constipation, feeling sick (dyspepsia), indigestion, stomach ache, stomach cramps or discomfort, feelings of fullness, bloating diarrhoea.
- Pain in your bones, muscles or joints.
- Headache.

Rare side effects (may affect up to 1 in 1000 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.

During post-marketing experience, the following have been reported

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

Not known (frequency cannot be estimated from available data):

- Hair loss
- Liver disorders, some cases were severe
- Inflammation of the small blood vessels

In rare cases the patients calcium and phosphate levels can be reduced in the beginning of the treatment. These changes are most often minor and does not give any symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system

listed in [To be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Risedronate Cipla

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

This medicinal product 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.

6. Contents of the pack and other information

What Risedronate Cipla contains

- The active substance is risedronate sodium. Each film coated tablet contains 35 mg risedronate sodium (as hemipentahydrate)
- The other ingredients (excipients) are:

Tablet core: lactose anhydrous, cellulose microcrystalline, croscarmellose sodium, magnesium stearate.

Film coating: hypromellose, titanium dioxide (E171), macrogol, iron oxide yellow (E172), iron oxide red (E172).

Risedronate Cipla looks like and contents of the pack

Light orange, approximately 4.2 mm in diameter, circular, biconvex, film coated tablets, plain on both sides.

Risedronate Cipla is available in PVC/Aluminum blisters

Pack sizes: 4 & 12s blister pack.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Cipla Europe NV
Uitbreidingstraat 80
2600 Antwerp
Belgium.

Manufacturer
Cipla (EU) Limited
20 Balderton street, LondonW1K 6TL, United Kingdom

S&D Pharma CZ,
spol. s r.o, Theodor 28, Pchery (Pharmos a.s. facility), 27308, Ceská Republika

Cipla Europe NV
Uitbreidingstraat 80, 2600 Antwerp, Belgium

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

Sweden	Risedronate Cipla
Spain	Risedranato Semanal Cipla 35 mg comprimidos recubiertos con pelicula EFG
France	RISEDRONATE CIPLA 35 mg, comprimé pelliculé
Italy	Risedronato Cipla

This leaflet was last revised in 28 December 2016