

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

RISEDRONATE 35 BIOTECH, Tablets

Risedronate sodium

Contains sugar. Each tablet contains 120,0 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking RISEDRONATE 35 BIOTECH

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- RISEDRONATE 35 BIOTECH has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What RISEDRONATE 35 BIOTECH is and what it is used for
2. What you need to know before you take RISEDRONATE 35 BIOTECH
3. How to take RISEDRONATE 35 BIOTECH
4. Possible side effects
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6. Contents of the pack and other information

1. What RISEDRONATE 35 BIOTECH is and what it is used for

RISEDRONATE 35 BIOTECH belongs to a group of medicines called bisphosphonates which are used to treat osteoporosis.

RISEDRONATE 35 BIOTECH is prescribed by medical practitioners to treat osteoporosis (thinning of the bone) in woman after menopause, in combination with calcium 500 to 1 000 mg per day.

Additional administration of vitamin D should be considered when deficiency might be expected.

2. What you need to know before you take RISEDRONATE 35 BIOTECH

Do not take RISEDRONATE 35 BIOTECH:

- if you are hypersensitive (allergic) to risedronate sodium or any of the other ingredients of RISEDRONATE 35 BIOTECH (see section 6)
- if you have been diagnosed with a condition called hypocalcaemia (deficiency of calcium in the blood)
- if you are pregnant or planning to become pregnant or if you are breastfeeding (see Pregnancy and breastfeeding)
- if you are suffering from severe kidney disease.

Warnings and precautions

Take special care with RISEDRONATE 35 BIOTECH:

- RISEDRONATE 35 BIOTECH will be prescribed to you if you have osteoporosis with low bone mineral density and/or a fracture
- if you are a very elderly patients (over the age of 80)
- if you have or have previously had problems with your throat, for instance you may have or have had pain or difficulty swallowing food
- if you have a history of stomach ulcers or indigestion

- immediately stop taking RISEDRONATE 35 BIOTECH tablets if you develop symptoms of oesophageal disease (such as difficulty or pain upon swallowing, retrosternal pain (pain behind the breastbone) or new or worsening heartburn) and consult your doctor
- 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) as you may need to take additional calcium and vitamin D during treatment with RISEDRONATE 35 BIOTECH
- if you are unable to stay in an upright position (sitting or standing) for at least 30 minutes
- if you had problems in the past with your oesophagus including 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)
- pay careful attention to the dosing instructions in HOW TO TAKE RISEDRONATE 35 BIOTECH below. Tell your doctor if you develop difficulty or pain on swallowing, new or worsening heartburn while taking RISEDRONATE 35 BIOTECH
- if you take any food, drinks or medicine containing calcium, magnesium, iron and aluminium (such as antacids for heartburn, nutritional supplements) as these may interfere with how RISEDRONATE 35 BIOTECH works. These products should not be taken at the same time as RISEDRONATE 35 BIOTECH (see Other medicine and RISEDRONATE 35 BIOTECH)
- RISEDRONATE 35 BIOTECH should be taken first thing in the morning at least 30 minutes before any food, drink or any other medicine other than water. Failing this, RISEDRONATE 35 BIOTECH, should be taken two hours either before or after the intake of any medicine, food or liquid
- if you have abnormal bone and mineral metabolism. Your doctor will treat this condition first before starting treatment with RISEDRONATE 35 BIOTECH. Your doctor may prescribe calcium and vitamin D as supplements
- if you have severe problems with your kidneys (see Do not take RISEDRONATE 35 BIOTECH)

- RISEDRONATE 35 BIOTECH may cause jaw-bone problems in some people. Jaw-bone problems may include infection, and delayed healing after teeth are pulled out or other work that involves drilling into the jaw. If you develop a toothache, jaw pain, painful exposed bone or swelling, especially following dental work, tell your doctor or dentist immediately
- if you have had or have pain, swelling or numbness of the jaw or a “heavy jaw feeling” or loosening of a tooth as your dentist will need to correct any of these problems before you start treatment with RISEDRONATE 35 BIOTECH.
- if you are under dental treatment or need to undergo dental surgery, tell your dentist that you are being treated with RISEDRONATE 35 BIOTECH. Invasive dental procedures should be avoided where possible
- if you are being treated for chronic ear conditions or have an ear injury
- unusual fracture of the thigh bone may occur particularly if you are on long-term treatment for osteoporosis. 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.

Your doctor may request tests or monitor your condition before and/or during treatment.

Other medicines and RISEDRONATE 35 BIOTECH

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Several medicines can cause unwanted reactions if used with RISEDRONATE 35 BIOTECH. Tell your doctor if you are using any medicine, in particular the following medicines:

- Aminoglycosides;
- Non-steroidal anti-inflammatory medicines;

- Medicines containing aluminium, calcium, iron or magnesium, including antacids, mineral supplements and osmotic laxatives.

Using RISEDRONATE 35 BIOTECH with NSAIDs may result in an increased incidence of digestive or renal adverse effects.

RISEDRONATE 35 BIOTECH may be used concomitantly with hormone replacement therapy.

RISEDRONATE 35 BIOTECH with food and drink

Food, drinks (other than plain water) and other products containing polyvalent cations (such as aluminium, calcium, iron or magnesium) decrease the absorption of RISEDRONATE 35 BIOTECH and should not be taken at the same time.

Therefore, RISEDRONATE 35 BIOTECH should be taken either, at least 30 minutes before the first food, or other medicine, or drink (other than plain water) of the day or, at least 2 hours away from food or drink at any other time of the day and at least 30 minutes before going to bed.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking RISEDRONATE 35 BIOTECH.

DO NOT take RISEDRONATE 35 BIOTECH if you are pregnant, suspect that you are pregnant or planning to become pregnant (see Do not take RISEDRONATE 35 BIOTECH).

DO NOT take RISEDRONATE 35 BIOTECH if you are breastfeeding your baby (see Do not take RISEDRONATE 35 BIOTECH).

There is no information available how RISEDRONATE 35 BIOTECH affects fertility in humans.

Driving and using machines

RISEDRONATE 35 BIOTECH should not have any effect on your ability to drive and use machinery.

It is not always possible to predict to what extent RISEDRONATE 35 BIOTECH may interfere with the daily activities of a patient. Do not operate machinery or drive a vehicle until you know how RISEDRONATE 35 BIOTECH affects you.

RISEDRONATE 35 BIOTECH contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking RISEDRONATE 35 BIOTECH.

3. How to take RISEDRONATE 35 BIOTECH

Do not share medicines prescribed for you with any other person.

Always take RISEDRONATE 35 BIOTECH exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

The dosage and dosage interval will be determined by your condition.

The recommended dose is one 35 mg tablet orally, once a week.

The tablet should be taken on the same day each week.

Food, drinks (other than plain water) and other products containing polyvalent cations (such as aluminium, calcium, iron or magnesium) decrease the absorption of RISEDRONATE 35 BIOTECH and should not be taken at the same time.

Therefore, RISEDRONATE 35 BIOTECH should be taken either, at least 30 minutes before the first food, or other medicine, or drink (other than plain water) of the day or, at least 2 hours away from food or drink at any other time of the day and at least 30 minutes before going to bed.

RISEDRONATE 35 BIOTECH should not be taken at bedtime or before getting up in the morning.

The tablets must be swallowed whole and not sucked or chewed.

You should take RISEDRONATE 35 BIOTECH while in an upright position (standing or sitting) with a glass of plain water (≥ 120 mL) to aid delivery to the stomach.

You should not lie down for 30 minutes after taking the tablet.

Take RISEDRONATE 35 BIOTECH preferably on arising in the morning.

Your doctor will tell you how long your treatment with RISEDRONATE 35 BIOTECH will last. If you have the impression that the effect of RISEDRONATE 35 BIOTECH is too strong or too weak, tell your doctor or pharmacist.

If you take more RISEDRONATE 35 BIOTECH than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take RISEDRONATE 35 BIOTECH

Do not take a double dose to make up for forgotten individual doses.

If you miss a dose, one RISEDRONATE 35 BIOTECH tablet should be taken on the day that the tablet is remembered. Patients should then return to taking one tablet once a week on the day the tablet is normally taken. Two tablets should not be taken on the same day.

Talk to your doctor or pharmacist if you have any questions about how to take RISEDRONATE 35 BIOTECH.

If you stop taking RISEDRONATE 35 BIOTECH

It is important that you continue the course of the treatment. Do not stop taking RISEDRONATE 35 BIOTECH unless your doctor tells you to do so.

4. Possible side effects

RISEDRONATE 35 BIOTECH can have side effects.

Not all side effects reported for RISEDRONATE 35 BIOTECH are included in this leaflet. Should your general health worsen while taking RISEDRONATE 35 BIOTECH, please consult your healthcare provider for advice.

If any of the following happens, stop taking RISEDRONATE 35 BIOTECH and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,

These are all very serious side effects. If you have them, you may have had a serious reaction to RISEDRONATE 35 BIOTECH. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- bruising easily (thrombocytopenia)
- weakness, fatigue, weight loss. headache (symptoms of a condition called vasculitis)
- Steven-Johnsons syndrome (a life-threatening skin disorder with symptoms such as a red-purplish rash and blisters)
- severe bone, joint or muscle pain

- thigh or groin pain (which may be side effect of a bone fracture)
- swelling in any part of the body

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- indigestion, nausea, vomiting, abdominal pain, diarrhoea, constipation, gastritis
- dry eyes, eye pain and inflammation, conjunctivitis (pink eye)
- headache
- pain

Less frequent side effects:

- anaemia (blood doesn't have enough healthy red blood cells), abnormal blood test results
- low serum calcium and phosphate levels
- pain, swelling, redness, or other signs of infection in the gums or sockets that don't heal after dental work
- abnormal vision, vision disturbances, swelling or irritation of the eye, blurred vision
- abnormal liver function test results
- skin rashes or other skin conditions, such as flushing, hives, itching, dry skin, and hair loss to serious skin conditions causing blisters and peeling, tissue damage
- pain and hearing problems (ear bone decaying)
- fever, chills, tiredness
- general feeling of discomfort or being unwell
- cancer of the oesophagus (the tube that takes food from the mouth to the stomach)

Side effects with unknown frequency:

- increase in some white blood cells (eosinophilia), lack of white blood cells, resulting in frequent infections such as fever, severe chills, sore throat or mouth ulcers (neutropenia)
- difficulty in sleeping (insomnia), sleepiness (somnolence)
- flatulence (excessive gas in the stomach or bowel), bleeding from the stomach wall, burping, painful swallowing
- serious liver disorders
- excessive sweating
- decreased libido
- acute mountain sickness with symptoms of dizziness, nauseous, and headache

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of RISEDRONATE 35 BIOTECH.

5. How to store RISEDRONATE 35 BIOTECH

Store all medicines out of reach of children.

Store at or below 25 °C in the original packing until intended for use.

Store in the original package container to protect from moisture.

Do not remove the blister from the outer carton until ready for use.

Do not use after the expiry date stated on the label/carton/bottle.

Do not use RISEDRONATE 35 BIOTECH if you notice that the tablets are damaged or don't look right in some way.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What RISEDRONATE 35 BIOTECH contains:

Active substance: Each film-coated tablet contains monosodium risedronate hemipentahydrate equivalent to 35mg risedronate sodium.

The other ingredients are lactose monohydrate (Flowlac 100), crospovidone, microcrystalline cellulose (PH 200), magnesium stearate and opadry orange consisting of Ferric oxide, yellow (E172), Ferric oxide, red (E172), hypromellose, macrogol and titanium dioxide (E171).

What RISEDRONATE 35 BIOTECH looks like and contents of the pack

Orange, oval, biconvex, film-coated tablet, encoded 35 on one side, approximately 11,6 x 5,8 mm in size.

White, HDPE containers with white tamper-evident screw caps containing 4 tablets or transparent PVC/ Al foil blister packs containing 4 tablets.

The blister strips are packed in the outer cardboard carton box.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Biotech Laboratories (Pty) Ltd.

Biotech Laboratories (Pty) Ltd.
Risedronate 35 Biotech – 43/3.2/1158
Each tablet contains 35 mg monosodium
risedronate hemipentahydrate equivalent to
35 mg risedronate sodium

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400 16th Road

Ground Floor, Block K West

Randjespark

Midrand, 1685

Gauteng

Tel. no.: +27 (0) 11 848 3050

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Access to the corresponding Professional Information

The Professional Information Leaflet is available from Biotech Laboratories (Pty) Ltd. To request a digital copy, please email info@biotechlabs.co.za.