

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is to be supplied by physician's prescription only

Risedronate S.K.

Film-coated tablet

Active ingredient - each tablet contains:
Risedronate sodium hemipentahydrate 150 mg.

Inactive ingredients and allergens: see section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

Do not give **Risedronate S.K.** to children or adolescents under 18 years of age. There have been no studies of this medicine's effects in this age group.

1. What is this medicine intended for?

The medicine is intended to treat and prevent osteoporosis in postmenopausal women.

Therapeutic group:

bisphosphonates.

Risedronate S.K. works directly on your bones to make them stronger and therefore less likely to break.

Osteoporosis

Osteoporosis (porous bone disease) is a disease that causes bones to become weaker. Weak bones break (fracture) more easily.

Osteoporosis is common in women after menopause and is also more likely to occur in women who have reached menopause early. Osteoporosis can also occur in women who have not yet reached menopause, and in men.

Long term steroid treatment can also lead to osteoporosis in both men and women.

Risedronate S.K. works by slowing down the process of old bone being removed.

This process allows the bone-forming cells time to rebuild normal bone.

Risedronate S.K. also helps to rebuild bone mass. This creates stronger bone which is less likely to fracture.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains.
- You are unable to remain in an upright position (sitting or standing) for 30 minutes after taking the medicine.
- You have hypocalcemia (low levels of blood calcium).
- You have an abnormality in your esophagus which makes emptying the esophagus slower, for example a narrowed esophagus or achalasia.

Special warnings about using this medicine

Before starting treatment with Risedronate S.K., tell your physician if you have any medical problems, especially if:

- You suffer, or have suffered in the past from:

- impaired function of the kidney
 - impaired function of the esophagus, such as an ulcer, or if you suffer from a syndrome called Barrett's esophagus, a condition in which there are changes in the cells of the lower esophagus
 - impaired function of the upper digestive tract
 - difficulty swallowing
 - problems in mineral metabolism of your bones (for example vitamin D deficiency, abnormal levels of the parathyroid hormone - both cause low calcium levels in the blood)
 - swelling, pain or sensitivity of the jaw
 - loose teeth or tooth loss
- You are presently undergoing dental procedures or are about to undergo dental surgery.
 - If there is anything that limits you from sitting or standing in an upright position.
 - You are pregnant, think you may be pregnant or plan to become pregnant. Use during pregnancy is not recommended.
 - You are breastfeeding or plan to breastfeed.

Warnings

- Tell every additional physician, dentist, or pharmacist that is treating you that you are taking **Risedronate S.K.**.
- If you are about to be started on any new medicine, tell your physician, dentist or pharmacist that you are taking **Risedronate S.K.**.
- Before starting treatment with bisphosphonates, a dental examination is recommended in patients with risk factors, for example: cancer patients, patients receiving chemotherapy or radiotherapy, patients receiving corticosteroids such as prednisone or cortisone, patients with poor oral hygiene.
- Inform your dentist that you are taking this medicine before starting dental treatment. As far as possible, avoid invasive dental procedures.
- This type of medicine may cause jaw-bone problems in some people. Jaw-bone problems may include infections and delayed healing after teeth are pulled out or after other treatment that involves drilling into the jaw.
- If you develop a toothache, jaw pain, pain or swelling in an exposed bone, especially following dental work, tell your physician or dentist immediately.
- Speak to your physician and dentist about good oral hygiene and regular dental check-ups while you are using **Risedronate S.K.**.
- If you are sensitive to any type of food or medicine, inform your physician before you start taking this medicine.

If you are taking or have recently taken other medicines, including non-prescription medication and nutritional supplements, inform your physician or pharmacist. In particular inform your physician or pharmacist if you are taking:

- antacids
- other products containing calcium
- iron supplements
- medicines that contain substances with a positive charge (divalent cations)

You may need to stop taking these products or take them at a different time of day than the time you take **Risedronate S.K.**.

Particularly, wait at least 30 minutes between taking Risedronate S.K. and taking other medicines or foods (see section 3 "How to use this medicine?").

Using this medicine and food

Swallow the medicine with a full glass of water, 30 minutes before breakfast.

Pregnancy and breastfeeding

Tell your physician if you are pregnant, think you may be pregnant, or are plan to become pregnant.

Do not take **Risedronate S.K.** if you are breastfeeding. It is not known whether **Risedronate S.K.** passes into breast milk.

3. How to use this medicine?

Always use according to the physician's instructions. Check with your physician or pharmacist if you are not sure. Only your physician will determine your dose and how you should take the medicine. The recommended dose is usually:

Take **Risedronate S.K.** on the same day each month. Choose a day of the month that suits you best.

Do not exceed the recommended dose.

Take **Risedronate S.K.** with a full glass of **tap water** first thing when you wake up in the morning, and at least 30 minutes before breakfast, before drinking anything (except for tap water), or before taking any medicine.

Risedronate S.K. is most effective when your stomach is empty.

Mineral water and other drinks, including fruit juices, soda, coffee and tea, will reduce the effect of **Risedronate S.K.**.

Take your **Risedronate S.K.** tablet while sitting or standing upright.

Do not lie down for 30 minutes after taking the medicine.

It is important to stay upright, for example, sitting, standing or walking around, for at least 30 minutes after swallowing your tablet. It is also very important to stay upright until after you have eaten your first food of the day. This will help make sure the tablet reaches your stomach quickly and helps avoid irritation to your esophagus.

Do not chew or suck the tablet!

While under treatment with this medicine, be sure to eat foods rich in calcium and vitamin D, such as dairy products. Take this medicine separately from calcium supplements.

Do not hold this medicine in your mouth longer than the time needed to swallow it. Failing to follow the instructions for taking this medicine may increase the risk of injury to your esophagus.

If you have accidentally taken a higher dose, or if a child has accidentally swallowed some medicine, go immediately to a hospital emergency room and bring the medicine package with you.

If you or somebody else has accidentally taken a large number of tablets, drink a full glass of milk or take antacids. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you forget to take the medicine at the scheduled time and the time remaining until your next monthly dose is longer than 7 days

- take a tablet the next morning.

If you forget to take the medicine at the scheduled time and the time remaining until your next monthly dose is 7 days or less

- do not take this dose. You must wait and take a tablet on the day of the month you chose to take your monthly treatment.

Persist the treatment as recommended by your physician.

If you are not sure what you should do, consult your physician or pharmacist.

If you have trouble remembering to take your medicine, consult your pharmacist.

How long you should take the medicine

Continue taking **Risedronate S.K.** for as long as your physician recommends it.

Do not stop treatment with this medicine without consulting your physician or pharmacist.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult your physician or pharmacist.

4. Side effects

Like all medicines, **Risedronate S.K.** may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Tell your physician or pharmacist as soon as possible if you do not feel well while you are taking **Risedronate S.K.**.

Stop treatment and immediately see a physician or go to a hospital emergency room if you notice:

- Symptoms of severe allergic reaction, such as:

- swelling of the face, lips, mouth, throat or tongue
- difficulty swallowing
- hives and difficulty breathing
- Severe skin reactions that can include blistering of the skin

These side effects could be serious. You may need urgent medical attention.

Stop treatment and refer immediately to the physician if you notice:

Rare side effects:

- Difficulty or pain in swallowing
- Chest pain
- New or worsening heartburn. These side effects may be due to irritation or ulcers in the esophagus. They may get worse if you continue taking the tablets.

Refer immediately to the physician if you notice:

Rare side effects:

- Skin irritation or rash
- Eye inflammation usually accompanied by pain, red eyes and sensitivity to light, blurred vision
- Jaw or teeth problems, associated with delayed healing and/or infection, usually following tooth extraction or an invasive dental procedure (see section “Warnings”)

Unusual fracture of the thigh bone, particularly in patients on long-term treatment for osteoporosis, may occur rarely. Contact your physician if you experience pain, weakness or discomfort in the thigh, hip or groin area as these signs may indicate a fracture of the thigh bone.

Additional side effects

Tell your physician or pharmacist if you notice any of the following:

Very common side effects:

- Gastrointestinal problems such as: indigestion, abdominal pain or discomfort, heartburn, diarrhea, bloating, nausea and constipation, feeling of fullness
- Pain, including back and joint pain

Side effects reported during marketing (unknown frequency):

- Hypersensitivity reactions
- Digestive tract side effects: effects related to irritation of the upper digestive tract, such as inflammation of the esophagus, ulcers in the esophagus or stomach
- Muscle and bone pain
- Eye inflammations
- Necrosis of the jaw bone
- Lung problems

If you experience a side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your physician.

You can report side effects to the Ministry of Health by following the link ‘Reporting Side Effects of Medication’ on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How to store the medicine?

- Store below 25°C.
- Product shelf-life: 36 months.
- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Even if stored as recommended, medicines keep for a limited period only. Please note the expiry date of this medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.
- Do not leave medicines in the car or on a window sill on hot days.

- Do not use the medicine if the packaging is torn or shows signs of tampering.
- Do not discard the medicine to the wastewater or household waste. Ask the pharmacist how to dispose of this medicine. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Microcrystalline cellulose, Crospovidone, Magnesium stearate, FD&C #2 Indigo Carmine Aluminum lake, Hydroxypropyl Cellulose, Hypromellose, Polyethylene Glycol/Macrogol, Silica, Titanium Dioxide.

What the medicine looks like and what are the contents of the package:

Blue, oval, film-coated tablet marked with 'RS' on one side and the number '150' on the other.

Each package contains 1 tablet.

License Holder:

KS Kim International Ltd., 7 Jabotinsky St., Ramat Gan.

Manufacturer:

Pharmscience Inc., 6111 Royalmount Avenue, Suite 100, Montreal (QC), H4P 2T4, Canada.

This leaflet was reviewed and approved by the Ministry of Health in December 2017.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
159-63-34827.