

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS
(PREPARATIONS(- 1986

The medicine is dispensed with a doctor's prescription only.

RISEDRONATE S.K.

Tablets

Composition:

Each **Risedronate S.K.** tablet contains: Risedronate sodium 150 mg

For the list of inactive and allergenic ingredients in the preparation, see section 2 "Important information regarding some of the ingredients of the medicine" and section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

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

This medicine is usually not intended for children or adolescents below 18 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

This medicine is intended for the treatment and prevention of osteoporosis in postmenopausal women. Therapeutic group: This medicine belongs to the therapeutic group of bisphosphonates.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine - see also section 6 "Further Information".
- you have certain esophagus problems.
- you are unable to remain in an upright position (sitting or standing) for at least 30 minutes after taking the medicine.
- you are in a state of hypocalcemia (low levels of blood calcium)

Special warnings regarding use of the medicine

Before treatment with **Risedronate S.K.**, inform the doctor if:

- you are suffering from swallowing problems.
- you are suffering from digestive problems.
- you have low blood calcium levels. In this condition, the doctor may prescribe for you calcium and vitamin D supplements during the course of treatment with **Risedronate S.K.**.

- you plan to have dental surgery or a tooth extraction. Maintain oral hygiene and go to a dental examination before starting the treatment.
- you have kidney problems.
- you have been told that you have trouble absorbing minerals in the stomach or intestines (malabsorption syndrome).
- you are pregnant, plan to become pregnant or suspect that you are pregnant. If you become pregnant during the course of treatment with **Risedronate S.K.**, stop treatment with the preparation and refer to your doctor.
- you are breastfeeding or plan to breastfeed.

Children and adolescents

This medicine is usually not intended for children or adolescents under 18 years of age.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist. Especially if you are taking:

- antacids.
- aspirin.
- nonsteroidal anti-inflammatory drugs (NSAIDs).

Use of the medicine and food

The medicine is only effective if taken on an empty stomach!

Wait at least 30 minutes between taking **Risedronate S.K.** and taking any preparations, nutritional supplements and food products or beverages (aside from tap water).

Pregnancy and breastfeeding

Pregnancy

here is inadequate information regarding use of the preparation during pregnancy. If you are pregnant, are planning to become pregnant, suspect you are pregnant or if you become pregnant during the course of treatment with **Risedronate S.K.**, stop treatment with the preparation and consult with a doctor.

Breastfeeding

There is inadequate information regarding use of the preparation while breastfeeding. If you are breastfeeding or plan to breastfeed, use of this preparation is not recommended; consult with a doctor.

Important information regarding some of the ingredients of the medicine

This medicine contains lactose, which may cause an allergy in people sensitive to lactose.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation. The dosage and treatment regimen will be determined by the doctor only.

This medicine is usually not intended for children and adolescents below 18 years of age. Recommended dosage, unless otherwise instructed by the doctor:

One **Risedronate S.K.** tablet, once a month, on a set date.

Do not exceed the recommended dose!

Take the tablet with a full glass of tap water, first thing upon rising in the morning, and at least 30 minutes before breakfast, before drinking any beverage (except for tap water) or before taking any medicine. Tap water is the only beverage that the preparation can be taken with. Do not take the medicine with mineral water since mineral water may contain high levels of calcium. Take the tablet while standing or sitting, do not lie down for 30 minutes after taking the medicine.

Do not chew or suck! Do not hold the medicine in your mouth for more than the time required to swallow it.

Failure to follow the instructions for taking the medicine may increase the risk of esophageal harm.

Use this medicine at set intervals, as determined by the attending doctor.

If you accidentally took a higher dosage, or if a child has accidentally swallowed the medicine, drink a full glass of milk, immediately proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine on the set day that was chosen, and the time remaining until the next monthly administration is more than 7 days - take a tablet the next morning. If you forgot to take the tablet at the set time and the time remaining until the next monthly administration is less than 7 days - do not take this dose, but wait and take the tablet on the day preset by you as the next monthly administration date.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not discontinue treatment with the medicine without consulting a doctor.

If you stop taking the medicine, your ailment may worsen.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them. If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Risedronate S.K.** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them. Severe side effects: Immediately stop using the preparation and refer to the doctor if you experience any of these effects:

- Esophagus problems - These problems can include irritation, inflammation or (sometimes bleeding) ulcer of the esophagus. To prevent these effects, see section 3 - "How should you use the medicine?".
- Chest pain, onset or worsening of existing heartburn, difficult or painful swallowing.
- Allergic reaction to the preparation. The symptoms can include: hives (an allergic skin reaction), swelling of the face, lips, tongue or throat.

Refer to a doctor immediately if you experience any of these effects:

- Hypocalcemia (low blood calcium levels) - **Risedronate S.K.** may lower blood calcium levels.

If you had low blood calcium levels before it may worsen the condition. In such a case, the blood calcium levels should be balanced before starting the treatment.

The symptoms that may occur in this case are:

- Spasms, twitches, or muscle cramps.
- Tingling in the fingers, toes or around the mouth.
- Onset of jaw bone problems (osteonecrosis).
- Bone, joint or muscle pain.
- Unusual thigh bone fractures - Symptoms that may occur in this case are: new or unusual pain in the hip, groin or thigh.

Additional side effects

Occur very frequently:

- Pain, including back and joint pain.
- Pain in the abdominal area.
- Heartburn.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects or by entering the following link: <https://sideeffects.health.gov.il>

Additionally, you can report to “S.K. Pharma.”

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- Store the medicine at a temperature that does not exceed 25° C and in a dry place protected from light.

6. FURTHER 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 the contents of the pack:

Risedronate S.K. is packaged in trays (blisters) which are inserted into a carton package. Each package contains 1 tablet.

Risedronate S.K. tablets are Blue, modified capsule-shape, coated tablets, debossed with "RS" on one side and "150" on the other side.

Manufacturer and address:

PHARMSCIENCE INC., CANADA

6111 ROYALMOUNT AVENUE, SUITE 100, MONTREAL (QC), H4P 2T4, CANADA

Registration holder and address :

K.S. KIM INTERNATIONAL (SK- PHARMA) LTD., ISRAEL

94 YIGAL ALON STR., TEL-AVIV-YAFO, 6789139

.

Revised in August 2023 according to MOH guidelines.

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