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

The dispensing of this medicine requires a doctor's prescription.

Read the package insert carefully in its entirety before using this medicine.

RISEDRONATE TEVA® 35 mg Tablets

COMPOSITION

Each tablet contains:
Risedronate Sodium 35 mg

Inactive ingredients:

Lactose monohydrate, pregelatinized starch, maize starch, colloidal silicon dioxide, sodium stearyl fumarate, magnesium stearate, polyvinyl alcohol, titanium dioxide (E171), macrogol, talc, iron oxide yellow (E172), iron oxide red (E172).

Each tablet contains 139.9 mg lactose.

THERAPEUTIC GROUP

Risedronate belongs to a group of medicines called bisphosphonates.

THERAPEUTIC ACTIVITY

Risedronate is used to treat and prevent osteoporosis in postmenopausal women and for treatment of osteoporosis in men at high risk of fractures.

WHEN SHOULD THE PREPARATION NOT BE USED?

Do not use Risedronate if you are pregnant, planning to become pregnant or breastfeeding.

Do not use Risedronate if you are sensitive to any of its ingredients.

Do not take this medicine if you are unable to remain in an upright position (standing or sitting) for at least 30 minutes after taking the medicine.

Do not use this medicine if you have difficulty swallowing for any reason.

Do not use this medicine if you are suffering from hypocalcemia (a low blood calcium level).

Do not use this medicine in patients suffering from severe renal failure (creatinine clearance less than 30 ml/min).

This medicine contains lactose, therefore should not be used if you suffer from problems of galactose intolerance, lactase deficiency, or glucose and lactose malabsorption.

Do not take this medicine without consulting a doctor before starting treatment

If you are suffering or have suffered in the past from impaired function of the kidney, the esophagus, from difficulty swallowing, if you are unable to sit or stand in an upright position. If you are suffering or have suffered in the past from swelling, pain or numbness of the jaw, loosened teeth or tooth loss, if you are under dental treatment or will undergo dental surgery, if you have an imbalance of minerals in the blood (such as lack of vitamin D or parathyroid hormone, both leading to a low blood calcium level).

WARNINGS

If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

It is recommended to undergo a dental check-up prior to commencing treatment with the medicine in patients with risk factors, such as: cancer patients, patients receiving chemotherapy or radiotherapy, patients receiving corticosteroids, patients with poor oral hygiene.

Inform your dentist that you are being treated with risedronate before starting dental treatment.

Patients on long term treatment with this medicine may suffer from fracture of the thigh bone (see Side Effects section).

DRUG INTERACTIONS

If you are taking another drug concomitantly or if you have just finished treatment with another medicine, including non-prescription medication or nutritional supplements, inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions.

Allow a lapse of at least 30 minutes between taking Risedronate Teva® and taking other medications or any food (including vitamins, herbal supplements and medicines obtained without prescription).

This medicine is effective only when taken on an empty stomach.

SIDE EFFECTS

In addition to the desired effect of the medicine, adverse reactions may occur during the course of using this medicine, for example: gastro-intestinal disturbances, such as: stomach ache, indigestion, bloating (flatulence), diarrhea, feeling sick, constipation, headache, pain in your joints, muscles or bones.

Effects that require special attention

Pain or difficulties when swallowing, inflammation or ulcer of the esophagus, chest pain, new or worsened heartburn (rare): stop treatment and refer to your doctor immediately!

Inflammation of the small intestine, of the stomach, of the tongue or the eyes (pain and redness often accompanied by visual disturbances) (rare): stop treatment and refer to your doctor.

Skin irritation or rash (rare): continue treatment and refer to your doctor immediately.

Eye inflammation usually with pain, redness, visual disturbances and sensitivity to light: refer to your doctor immediately.

Severe allergic reaction that can include skin rash, swelling of the face, throat or tongue, difficulties in swallowing and breathing: stop treatment and refer to your doctor immediately!

Jaw bone problems (osteonecrosis) associated with delayed healing and infection, often following tooth extraction: refer to your doctor immediately.

Abnormal liver function tests, liver function disorders, hair loss (rare): refer to your doctor immediately.

Thigh pain, weakness or discomfort may be an early indication of a possible fracture of the thigh bone: refer to your doctor immediately.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

DOSAGE

Dosage is according to doctor's instructions only. Do not exceed the recommended dosage.

Take one Risedronate Teva® 35 mg tablet once a week, whilst you are in an upright position (sitting or standing), with a full glass of tap water (not mineral water, not tea/coffee and not juice).

Do not lie down for 30 minutes after taking this medicine (in order to avoid heartburn).

Swallow the tablet first thing upon getting up in the morning, at least 30 minutes before having breakfast, before drinking any beverage (except for tap water) or taking any other medicine.

Choose one day of the week that best fits your schedule and take one Risedronate Teva® 35 mg tablet, on your chosen day each week.

This medicine is not usually intended for administration to children under 18 years of age.

This medicine is to be taken at specific time intervals as determined by the attending doctor.

If you forget to take this medicine on your chosen day, take the tablet on the morning of the day after you remember, then return to taking one tablet once a week, on your chosen day as originally scheduled.

Never take two tablets in one day.

During treatment with this medicine take care to eat a diet rich in calcium and vitamin D, such as dairy products.

DIRECTIONS FOR USE

Do not chew or suck! Do not crush or divide the tablet! Swallow the tablet with a full glass of tap water only (see above).

Do not hold the tablet in your mouth longer than the time required for swallowing.

Failure to follow these instructions for the intake of this medicine may increase the risk of damaging the esophagus.

HOW CAN YOU CONTRIBUTE TO THE SUCCESS OF THE TREATMENT?

Complete the full course of treatment as instructed by the doctor.

Even if there is an improvement in your health, do not discontinue use of this medicine without consulting your doctor.

AVOID POISONING!

This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, in order to avoid poisoning.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

Do not induce vomiting unless explicitly instructed to do so by a doctor!

This medicine has been prescribed for the treatment of your ailment; in another patient it may cause harm.

Do not give this medicine to your relatives, neighbors or acquaintances.

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

STORAGE

Store this medicine in a dry place, below 25°C.

Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.

Do not store different medications in the same package.

Drug Registration No.:

096.63.31173



Manufacturer:

Teva Pharmaceutical Works Private Ltd. Company, Hungary.

License Holder:

Abic Marketing Ltd., P.O.B. 8077, Netanya.

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