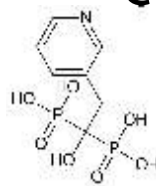


RX RISEDRONATE

[Each film-coated tablet contains 30 mg risedronate sodium (equivalent to 27.8 mg risedronic acid)]



GENERIC NAME: risedronate

DRUG CLASS AND MECHANISM

Risedronate is in a class of drugs called bisphosphonates which also includes the drugs alendronate (Fosamax) and etidronate (Didronel). It is used for the treatment of Paget's disease of bone (a disease in which the formation of bone is abnormal) and in persons with osteoporosis (in which the density and strength of bones are reduced). Bone is continually being formed and dissolved. By slowing down the rate at which bone is dissolved, risedronate increases the amount of bone. Risedronate has a chemically unique component as compared with the other bisphosphonates which is believed to reduce the likelihood of gastro-intestinal side effects. Risedronate is more potent in blocking the dissolution of bone than etidronate and alendronate. The FDA approved risedronate for treatment of Paget's disease in 1998 and for the prevention and treatment of osteoporosis in 1999.

PRESCRIPTION: yes

PREPARATIONS: Tablets of 5, 30, and 35 mg.

PRESCRIBED FOR

Risedronate is used for the treatment of Paget's disease of bone (osteitis deformans) and to treat or prevent osteoporosis. It is also used to prevent and treat osteoporosis that is caused by cortisone-related medications (glucocorticoid-induced osteoporosis).

DOSING

For osteoporosis, 5 mg of risedronate is taken once daily or 35 mg is taken weekly with 6 to 8 ounces of plain water. For Paget's disease, initial treatment is 30 mg daily for two months. Because food interferes with the absorption of risedronate, it should be taken first thing in the morning before anything is eaten or drunk. Also, no food or drink should be taken for at least 30 minutes afterwards. To avoid pills sticking and irritating the throat or esophagus, persons should not lie down for at least 30 minutes after taking risedronate. It should also not be taken at the same time as iron supplements, vitamins with minerals, or antacids containing calcium, magnesium, or aluminum.

DRUG INTERACTIONS

See also the How to Use section. Your healthcare professionals (e.g., doctor or pharmacist) may already be aware of any possible drug interactions and may be monitoring you for it. Do not start, stop or change the dosage of any medicine before checking with them first. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use. Check the labels on all your medicines because they may contain aspirin or nonsteroidal anti-inflammatory drugs (NSAIDs such as ibuprofen, naproxen) that could cause stomach irritation/ulcers. Ask your pharmacist about the safe use of those products. Low-dose aspirin, as prescribed by your doctor for specific medical reasons such as heart attack or stroke prevention (usually these dosages are 81-325 milligrams per day), should be continued. Consult your doctor or pharmacist for more details. This medication may affect the results of certain lab tests (bone-imaging agents). Be sure to tell your doctor or laboratory personnel that you are taking this medication. This document does not contain all possible interactions. Therefore, before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist.

USES

Risedronate is used to prevent and treat certain types of bone loss (osteoporosis) in adults. Osteoporosis causes bones to become thinner and break (fracture) more easily. Your chance of developing osteoporosis increases as you age, after menopause, or if you are taking corticosteroid medications (e.g., prednisone) for long periods of time. This medication works by slowing bone loss to help maintain strong bones and reduce the risk of fractures. Risedronate belongs to a class of medications called bisphosphonates.

HOW TO USE

Read the Patient Information Leaflet provided by your pharmacist before you start using risedronate and each time you get a refill. Follow the instructions very closely to maximize the amount of drug absorbed and reduce the risk of injury to your esophagus. Consult your doctor or pharmacist if you have any questions. Take this medication by mouth, usually once a day or as directed by your doctor. Take it after getting up for the day and before taking your first food, beverage or other medication. Do not take it at bedtime or while you are still in bed. Take this medication with a full glass (6-8 ounces or 180-240 milliliters) of plain water. Do not take it with any other beverage. Swallow the tablet whole. Do not chew or suck on it. Then stay fully upright (sitting, standing or walking) for at least 30 minutes, and do not lie down until after your first food of the day. Wait at least 30 minutes after taking risedronate before you eat or drink anything other than plain water and before taking any other medication by mouth. Calcium or iron supplements, vitamins with minerals, antacids containing calcium/magnesium/aluminum, dairy products (e.g., milk, yogurt), and calcium-enriched juice may interfere with absorption of risedronate. Medications such as quinapril, certain forms of didanosine (chewable/dispersible buffered tablets or pediatric oral solution), sucralfate, and bismuth subsalicylate may also interfere with absorption. Do not take these products for at least 30 minutes after taking risedronate. Use this medication regularly in order to get the most benefit from it. Remember to take it at the same time each morning.

SIDE EFFECTS

Upset stomach or headache may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: bone/joint/muscle pain, jaw pain, eye/vision problems. This medication may infrequently cause irritation and ulcers in your stomach or esophagus. Seek immediate attention if any of these serious side effects occur: new/severe/worsening heartburn, chest pain, difficult or painful swallowing, severe stomach/abdominal pain, black/tarry stools, vomit that looks like coffee grounds. A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS

Before taking risedronate, tell your doctor or pharmacist if you are allergic to it; or to other bisphosphonates (e.g., alendronate, etidronate, pamidronate); or if you have any other allergies. This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have the following conditions: low blood calcium levels (hypocalcemia), inability to sit upright or stand for at least 30 minutes, severe kidney disease. Before using this medication, tell your doctor or pharmacist your medical history, especially of: esophagus problems (e.g., esophageal stricture), difficult or painful swallowing, kidney problems, stomach/intestinal disorders (e.g., ulcers). Infrequently, serious jawbone problems (osteonecrosis) have occurred in people taking similar medications. Most people were also using other medications or had conditions that actually caused the jawbone problem. If you have cancer, anemia, blood clotting disorders, infections in the mouth or other diseases of the mouth, or poor dental hygiene, see your dentist for a full examination/treatment before you start risedronate. Make sure your dentist knows your entire medical history, including any cancer radiation treatments. Also tell your dentist of all the medications you are using, especially corticosteroids such as prednisone, cancer chemotherapy, and risedronate. Consult your dentist for more details. Caution is advised if you are pregnant or planning to become pregnant in the future. This medication may stay in your body for many years. Its effects on an unborn baby are not known. Discuss the risks and benefits with your doctor before starting treatment with risedronate. It is not known if this medication passes into breast milk. Consult your doctor before breast-feeding. **OVERDOSE**

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

MISSED DOSE

If you miss a dose, skip the missed dose. Do not take it later in the day. Resume your usual dosing schedule the following day. Do not double the dose to catch up.

STORAGE

Store the US product at room temperature between 68-77 degrees F (20-25 degrees C). Store the Canadian product at room temperature between 59-86 degrees F (15-30 degrees C). Store the medication away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

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