

**Orek® 70 mg  
(Alendronate) 70 mg**

**What is Orek® 70mg ?**

**Composition per tablet:**

Alendronate Sodium Trihydrate corresponding to 70mg of Alendronic Acid. Excipients: Gelatine, Silicon Dioxide, Magnesium Stearate, Lactose, Corn Starch, Sodium Croscarmellose

**Therapeutic action:**

Alendronate is an inhibitor of osteoclast-mediated bone resorption.

**What is Orek® 70 mg indicated for?**

Orek® 70mg is indicated for the:

- Treatment and prevention of osteoporosis in post-menopausal women, with a bone mineral density of at least 2 standard deviations (2SD) below the average in healthy post-menopausal women or the presence or history of fractures caused by osteoporosis
- Treatment to increase bone mass in men with osteoporosis
- Treatment of glucocorticoid-induced osteoporosis in men and women receiving glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and who have low bone mineral density. Patients treated with glucocorticoids should receive adequate amounts of calcium and vitamin D.
- Treatment of Paget's disease of bone in men and women

**What should I discuss with my healthcare provider before taking Orek® 70 mg?**

Before using Orek® 70 mg, tell your doctor if you have:

- low blood calcium (hypocalcemia),
- a vitamin D deficiency,
- kidney disease, or
- an ulcer in your stomach or esophagus or any esophagus abnormalities such as stricture or achalasia.

If you have any of these conditions, you may not be able to use Orek® 70 mg, or you may need a dosage adjustment or special tests during treatment.

This medication may be harmful to an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant during treatment. It is not known whether alendronate passes into breast milk or if it could harm a nursing baby. Do not use this medication without telling your doctor if you are breastfeeding a baby.

**How should I take Orek® 70 mg?**

Take Orek® 70 mg exactly as it was prescribed for you. Do not use the medication in larger amounts or for longer than recommended by your doctor.

Orek® 70 mg tablets are taken once each week. Take it on the same day of each week and always first thing in the morning. Use only plain water (not mineral water). Do not crush, chew, or suck the Orek® 70 mg tablet. Swallow the pill whole.

After taking Orek® 70 mg tablet, carefully follow these instructions:

- Do not lie down or recline for at least 30 minutes
- Do not eat or drink anything other than plain water
- Do not take any other medicines including vitamins, calcium, or antacids for at least 30 minutes. It may be best to take your other medicines at a different time of the day. Talk with your doctor about the best dosing schedule for your other medicines.

To be sure this medication is helping your condition, your bone mineral density will need to be tested on a regular basis. It is important that you do not miss any scheduled visits to your doctor.

Orek® 70 mg is only part of a complete program of treatment that may also include diet changes, exercise, and taking calcium and vitamin supplements. Follow your diet, medication, and exercise routines very closely.

Store Orek® 70 mg tablets at room temperature away from moisture, heat and light. **KEEP AWAY FROM THE REACH OF CHILDREN**

**What happens if I miss a dose?**

If you forget to take Orek® 70 mg on your scheduled day, take it first thing in the morning on the day after you remember the missed dose. Then return to your regular weekly schedule on your chosen dose day. Do not take two (2) tablets in one day.

**What happens if I overdose?**

Seek emergency medical attention if you think you have used too much of this medicine. Drink a full glass of milk and call your local poison control center or emergency room right away. Do not make yourself vomit and do not lie down.

Symptoms of an alendronate overdose may include nausea, heartburn, stomach pain, diarrhea, muscle cramps, numbness or tingling, tight muscles in your face, seizure (convulsions), irritability, and unusual thoughts or behavior.

**What should I avoid while taking Orek® 70 mg?**

Do not take any other medicines including vitamins, calcium, or antacids for at least 30 minutes after taking Orek® 70 mg. Do not lie down for at least 30 minutes after you take an alendronate tablet.

## Orek® 70 mg side effects

Get emergency medical help if you have any of these signs of an allergic reaction: hives; difficulty breathing; swelling of your face, lips, tongue, or throat. Stop using Orek® 70 mg and call your doctor at once if you have any of these serious side effects:

- chest pain,
- difficulty or pain when swallowing,
- pain or burning under the ribs or in the back,
- new or worsening heartburn,
- severe joint, bone, or muscle pain, or
- jaw pain, numbness, or swelling.

Continue using Orek® 70 mg and talk with your doctor if you have any of these less serious side effects:

- mild heartburn or stomach upset,
- diarrhea, gas, or constipation,
- joint pain or swelling,
- swelling in your hands or feet,
- back pain, or
- dizziness, weakness, or headache.

Side effects other than those listed here may also occur. Talk to your doctor about any side effect that seems unusual or that is especially bothersome.

## What other drugs will affect Orek® 70 mg?

Antacids, supplements, or medicines that contain aluminum, calcium, magnesium, or other minerals can interfere with how your body absorbs alendronate. If you use these other medicines, do not take them for at least 30 minutes after taking Orek® 70 mg tablet.

Before using Orek® 70 mg, tell your doctor if you also use aspirin or other NSAIDs (non-steroidal anti-inflammatory drugs) such as celecoxib (Celebrex), diclofenac (Voltaren), diflunisal (Dolobid), ibuprofen (Motrin, Advil), indomethacin, ketoprofen (Orudis), ketorolac (Toradol), naproxen (Aleve, Naprosyn), piroxicam (Feldene), and others.

There may be other drugs that can affect alendronate. Tell your doctor about all the prescription and over-the-counter medications you use. This includes vitamins, minerals, herbal products, and drugs prescribed by other doctors. Do not start using a new medication without telling your doctor.

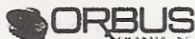
## What does my medication look like?

Alendronate is available with a prescription under the brand name Orek® 70 mg supplied in packs of 8 tablets.

## Marketing Authorisation Holder in Lebanon:

Pharmadex S.A.L, Kahaleh, Lebanon

## Manufactured by:



20 KONRAD CRESCENT, MARKHAM, ONTARIO, L3R 8T4, CANADA

### THIS IS A MEDICINE

A medicine is a product which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold you the medicine.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

### إن هذا الدواء

مستحضر يؤثر على صحتك واستهلاكه خلافاً للتعليمات يعرضك للخطر. اتبع بدقة وصفة الطبيب وطريقة الاستعمال المنصوص عليها وتعليمات الصيدلي الذي صرفها لك.

- الطبيب والصيدلي هما الخبيران في الدواء وفي نفعه وضرره.
- لا تقطع مدة العلاج المحددة لك من تلقاء نفسك.
- لا تكرر صرف الدواء بدون استشارة الطبيب.
- لا تترك الادوية في متناول الاطفال.