

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

The medicine is dispensed with a doctor's prescription only

Alendronate Teva 70 mg Tablets

Each tablet contains:

Alendronate Sodium Monohydrate 81.2 mg (equivalent to 70 mg Alendronic acid)

For information about inactive ingredients, see section 2 - "Important information about some of the ingredients of the medicine" and section 6 - "Further Information".

Read this 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 as treatment 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.

This medicine is not intended for children, see also section 2 - "Before Using The Medicine".

Alendronate Teva is intended for the treatment of women only after menopause. Do not take Alendronate Teva if you are pregnant or think you may be pregnant, or if you are breast-feeding.

1. WHAT IS THE MEDICINE INTENDED FOR?

Alendronate Teva is indicated:

- For treatment of osteoporosis in postmenopausal women, to prevent fractures.
- For treatment to increase bone mass in men with osteoporosis.

Therapeutic group: Bisphosphonates.

It is not known how long you need to take Alendronate Teva for the treatment of osteoporosis. You should see your doctor regularly to determine if Alendronate Teva is still suitable for you.

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 (for a list of the inactive ingredients, see section 6 - "Further Information").
- you have certain problems with the esophagus (the tube that connects your mouth to your stomach).
- you are unable to stand or sit upright for at least 30 minutes.
- you have low blood calcium levels.

Special warnings regarding use of the medicine:

Before treatment with Alendronate Teva, tell your doctor if:

- you have problems with swallowing
- you have stomach or digestive problems
- you have low blood calcium levels
- you plan to undergo dental surgery or tooth extraction
- you have gum disease, oral health problems
- you smoke or have smoked in the past (since this could increase the risk of dental problems)
- you have kidney problems
- you have been told that you have a problem absorbing minerals in the stomach or intestines (malabsorption syndrome)
- you have cancer
- you are pregnant or are planning to become pregnant. It is not known whether Alendronate Teva can harm your unborn baby
- you are breast-feeding or are planning to breast-feed. It is not known if Alendronate Teva passes into your breast milk and whether it could harm your baby

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the attending doctor or pharmacist. In particular, tell your doctor if you are taking:

- Antacids
- Aspirin
- Non-steroidal anti-inflammatory drugs (NSAIDs)
- Chemotherapy or radiotherapy
- Corticosteroids (such as prednisone or dexamethasone)

Know the medicines that you are taking. Keep a list of them, and show it to your doctor and pharmacist every time you get a new medicine. Certain medicines may affect how Alendronate Teva works.

After swallowing an Alendronate Teva tablet, wait at least 30 minutes before taking other medicines, including antacids, calcium, other dietary supplements and vitamins. Alendronate Teva is effective only if taken on an empty stomach.

Use of the medicine and food:

Take Alendronate Teva after getting up in the morning and before eating the first food of the day, drinking a beverage or taking another medicine.

Take an Alendronate Teva tablet with a full glass (at least 200 ml) of tap water.

Do not take Alendronate Teva with mineral water, coffee, tea, soda or juice.

After swallowing Alendronate Teva, wait at least 30 minutes before eating the first food or drinking the first beverage of the day, except for tap water.

Pregnancy and breast-feeding

Before commencing treatment with Alendronate Teva, tell your doctor if:

- you are pregnant or are planning to become pregnant. It is not known whether Alendronate Teva can harm your unborn baby
- you are breast-feeding or are planning to breast-feed. It is not known if Alendronate Teva passes into your breast milk and whether it could harm your baby

Driving and operating machinery

There are side effects (including blurred vision, dizziness and severe bone, muscle or joint pain) that have been reported with Alendronate, which could affect the ability to drive or operate machinery. If you experience any of these side effects, do not drive until you feel better.

Important information about some of the ingredients of the medicine

This medicine contains less than 23 mg of sodium per tablet, and is therefore considered to be sodium free.

Children

Alendronate Teva is not intended for use in children.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.

The dosage and treatment regimen will be determined by the doctor only.

The usually recommended dose is: One Alendronate Teva tablet once a week.

Do not exceed the recommended dosage.

- **Alendronate Teva only works if taken on an empty stomach.**
- Choose the day of the week that best fits your schedule.
- Take one Alendronate Teva tablet once a week on the day you have chosen, **after** getting up in the morning and **before** eating the first food of the day, drinking a beverage or taking another medicine.
- Take Alendronate Teva when sitting or standing.
- **Do not halve, crush, chew or suck the Alendronate Teva tablet, as mouth ulcers could occur.**
- Swallow the Alendronate Teva tablet with a full glass (at least 200 ml) of tap water only.
- **Do not** take Alendronate Teva with mineral water, coffee, tea, soda, or juice.

After swallowing Alendronate Teva, wait at least 30 minutes:

- Before lying down. You may sit, stand or walk and perform regular activities such as reading.
- Before eating the first food or drinking the first beverage of the day, except for tap water.
- Before taking other medicines, including antacids, calcium, dietary supplements and other vitamins.

Do not lie down for at least 30 minutes after taking Alendronate Teva and until after eating the first food of the day.

If you accidentally take too high a dose

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

Do not try to vomit, do not lie down.

If you forget to take the medicine

If you forgot to take a dose of Alendronate Teva, do not take it later on the same day. Take the forgotten dose the next morning and return to your regular schedule. Do not take two doses on the same day.

Complete the treatment as recommended by the doctor.

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

Do not take medicines in the dark! Check the label and the dose each time you take a 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 Alendronate Teva may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Alendronate Teva may cause serious side effects, including:

1. Esophagus problems
2. Low blood calcium levels (hypocalcemia)
3. Severe bone, joint or muscle pain
4. Severe jaw bone problems (osteonecrosis)
5. Unusual fractures of the thigh bone
6. Allergic reactions and severe skin reactions

Stop taking Alendronate Teva and refer to the doctor immediately if you develop any of the following signs:

1. Esophagus problems

Some people who take Alendronate may develop problems in the esophagus (the tube that connects the mouth to the stomach). These problems include irritation, inflammation or ulcers of the esophagus which may sometimes bleed.

- It is important that you take Alendronate Teva exactly as determined by the doctor in order to help lower the chance of suffering from esophagus problems (see section 3 "How should you use the medicine?").
- **Stop taking Alendronate Teva and contact your doctor immediately if you develop chest pain, new heartburn or worsening of heartburn, or if you have difficulties or pain when swallowing.**

Refer to the doctor as soon as possible if you develop any of the following signs:

2. Low blood calcium levels (hypocalcemia)

Alendronate Teva may lower your blood calcium levels. If you have a low blood calcium level before you start taking Alendronate Teva, it may get worse during the treatment. The low blood calcium level must be treated before you take Alendronate Teva. Most people with low blood calcium levels do not have symptoms, though some may have symptoms. Contact your doctor immediately if you have symptoms of low blood calcium levels, such as:

- Spasms or cramps in your muscles
- Numbness or tingling in your fingers, toes, or around your mouth

Your doctor may prescribe calcium and vitamin D to help prevent low calcium levels in your blood while you are taking Alendronate Teva. Take calcium and vitamin D in accordance with your doctor's instructions.

3. Severe bone, joint or muscle pain

4. Severe jaw bone problems (osteonecrosis)

Severe jaw bone problems may occur while taking Alendronate Teva. Jaw bone problems may include infection and delayed healing after tooth extraction.

Your doctor should examine your mouth before beginning treatment with Alendronate Teva. Your doctor may refer you to your dentist before beginning treatment with Alendronate Teva. It is important to be meticulous with good mouth care during treatment with Alendronate Teva.

5. Unusual fractures of the thigh bone

Unusual fractures of the thigh bone occurred in some people. Symptoms of a fracture could include new or unusual pain in your hip, groin, or thigh.

6. Allergic reactions and severe skin reactions

Allergic reactions such as hives, swelling of the face, lips, tongue and/or throat (which could cause difficulty breathing or swallowing) and severe skin reactions.

Contact your doctor immediately if you have any of these side effects.

The most common side effects of Alendronate Teva are:

- Pain in the abdominal area
- Heartburn
- Constipation
- Diarrhea
- Upset stomach
- Bone, joint or muscle pain
- Nausea

Less common side effects are vomiting, a feeling of bloating or fullness in the stomach, black or bloody stools, flatulence, itching or pain in the eye, inflammation of the uvea (uveitis), scleritis (inflammation of the eye's sclera), episcleritis (inflammation of the wall of the eye), rash that may be made worse by exposure to sunlight, hair loss, headache, dizziness, a change in sense of taste, and joint swelling or swelling of the hands or legs.

Other possible side effects:

- Mouth sores (ulcers) may occur if the Alendronate Teva tablet is chewed or dissolved in the mouth.
- You may have flu-like symptoms, typically at the start of treatment with Alendronate Teva.
- Worsening of asthma has been reported.
- Rarely, stomach or other peptic ulcers (some severe with bleeding) have occurred.
- Talk to your doctor if you have ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear.

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 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 link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should 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 the 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.
- **Storage Conditions:** Store this medicine in a dry place, below 25°C.
- Do not dispose of medicines via wastewater or a household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help to protect the environment.

6. FURTHER INFORMATION

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

Microcrystalline cellulose, croscarmellose sodium, magnesium stearate.

What the medicine looks like and contents of the package

The Alendronate Teva 70 mg tablet is a round tablet with beveled edges, white to off-white in color, smooth on both sides. The package of the medicine contains 4 tablets in a tray (blister).

Name of License Holder and Manufacturer and its Address:

Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petah-Tikva. This leaflet was checked and approved by the Ministry of Health in October 2014 and updated in accordance with the Ministry of Health guidelines in June 2019.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

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