

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

This medicine is marketed upon physician's prescription only

FOSAVANCE[®] 70 mg/5600 IU Tablets

Each tablet contains:

Alendronic Acid 70 mg (as alendronate sodium trihydrate)
Cholecalciferol (Vitamin D₃) 140 microgram (5600 IU)

For a list of inactive ingredients see section 6 "**Further information**". See also section 2.7, "**Important information about some of the ingredients of FOSAVANCE**".

Read all of this leaflet carefully before you start taking this medicine.

- This leaflet contains concise information about **FOSAVANCE**. If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their medical condition seems similar to yours.
- This medicine is not intended for children. See also section 2.8.
- **FOSAVANCE** is only intended for use in women after menopause. You should not take **FOSAVANCE** if you are pregnant or think you may be pregnant, or if you are breast-feeding.

1. WHAT IS FOSAVANCE INTENDED FOR?

FOSAVANCE is indicated for:

- the treatment of osteoporosis in women after menopause. **FOSAVANCE** helps increase bone mass and reduces the chance of having a hip or spinal fracture (break).
- treatment to increase bone mass in men with osteoporosis.

Therapeutic group: **FOSAVANCE** is a tablet containing the two active substances: alendronic acid, that belongs to a non-hormonal medicines class called bisphosphonates, and cholecalciferol known as vitamin D₃.

FOSAVANCE should not be used to treat vitamin D deficiency.

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

2. BEFORE YOU TAKE FOSAVANCE

2.1 Do not take FOSAVANCE if you:

- Are hypersensitive (allergic) to alendronate sodium or to cholecalciferol or to any of the other ingredients of **FOSAVANCE** (for a list of inactive ingredients, see section 6 "**Further information**")
- Have certain problems with your esophagus (the tube that connects your mouth with your stomach)
- Cannot stand or sit upright for at least 30 minutes
- Have low levels of calcium in your blood

2.2 Special warnings concerning use of FOSAVANCE

Before starting treatment with FOSAVANCE tell your doctor if you:

- Have problems with swallowing
- Have stomach or digestive problems
- Have low blood calcium
- Plan to have dental surgery or teeth removed
- Have gum disease, oral health problems

- Are or have been a smoker (as this may increase the risk of dental problems)
- Have kidney problems
- Have sarcoidosis, leukemia, lymphoma. These conditions may cause changes in vitamin D
- Have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome)
- Have cancer
- Are pregnant, trying to become pregnant or suspect that you are pregnant. If you become pregnant while taking **FOSAVANCE**, stop taking it and contact your doctor
- Are breast-feeding or plan to breast-feed

2.3 Drug interactions

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

Especially tell your doctor or pharmacist if you take:

- antacids
- aspirin
- Nonsteroidal Anti-Inflammatory (NSAID) medicines
- chemotherapy or radiotherapy
- corticosteroids (such as prednisone or dexamethasone)

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist each time you get a new medicine. Certain medicines may affect how **FOSAVANCE** works.

After swallowing your FOSAVANCE tablet, wait at least 30 minutes before you take other medicines, including antacids, calcium, and other supplements and vitamins. **FOSAVANCE** works only if taken on an empty stomach.

2.4 Taking FOSAVANCE with food and drink

Take **FOSAVANCE** **after** you get up for the day and **before** taking your first food, drink, or other medicine. Take your **FOSAVANCE** tablet with a full glass (not less than 200 ml) of plain water.

Do not take **FOSAVANCE** with mineral water, coffee, tea, soda, or juice.

After swallowing **FOSAVANCE**, wait at least 30 minutes before you take your first food or drink except for plain water.

2.5 Pregnancy and breast-feeding

FOSAVANCE is only intended for use in women after menopause. You should not take **FOSAVANCE** if you are pregnant or think you may be pregnant, or if you are breast-feeding.

2.6 Driving and using machines

There have been side effects (such as blurred vision, dizziness and severe bone, muscle or joint pain) reported with **FOSAVANCE** that may affect your ability to drive or operate machinery. If you experience any of these side effects, you should not drive until you feel better.

2.7 Important information about some of the ingredients of FOSAVANCE

FOSAVANCE tablets contain lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine (see also section 6, "**Further information**").

2.8 Children

FOSAVANCE is not for use in children.

3. HOW TO TAKE FOSAVANCE?

Always take **FOSAVANCE** as instructed by the doctor. You should check with your doctor or pharmacist if you are not sure about your dose and about how to take this medicine.

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

The usually recommended dose is: 1 tablet of **FOSAVANCE** 1 time a week.

Do not exceed the recommended dose.

- **FOSAVANCE works only if taken on an empty stomach.**
- Take 1 tablet of **FOSAVANCE** 1 time a week, **after** you get up for the day and **before** taking your first food, drink, or other medicine.
- Take **FOSAVANCE** while you are sitting or standing.
- Take your **FOSAVANCE** tablet with a full glass (not less than 200 ml) of plain water.
- **Do not crush or chew or suck on a tablet of FOSAVANCE since mouth ulcers can occur.**
- No information is available regarding splitting of tablets.
- **Do not** take **FOSAVANCE** with mineral water, coffee, tea, soda, or juice.
- Do not take **FOSAVANCE** at bedtime.

After swallowing **FOSAVANCE**, wait at least 30 minutes:

- Before you lie down. You may sit, stand or walk, and do normal activities like reading.
- Before you take your first food or drink except for plain water.
- Before you take other medicines, including antacids, calcium, and other supplements and vitamins.

Do not lie down for at least 30 minutes after you take FOSAVANCE and after you eat your first food of the day.

If you take more FOSAVANCE than you should

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or 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 FOSAVANCE

If you miss a dose of **FOSAVANCE**, do not take it later in the day. Take your missed dose on the next morning after you remember and then return to your normal schedule. Do not take 2 doses on the same day.

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 before consulting your doctor.

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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS

Like all medicines, **FOSAVANCE** can cause side effects, in some of the users.

Do not be alarmed by reading the list of side effects, you may not suffer from any of them.

FOSAVANCE can cause serious side effects including:

1. Esophagus problems
2. Low calcium levels in your blood (hypocalcemia)
3. Severe bone, joint, or muscle pain

4. Severe jaw bone problems (osteonecrosis)
5. Unusual thigh bone fractures
6. Allergic reactions, and severe skin reactions

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

1. Esophagus problems.

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

- It is important that you take **FOSAVANCE** exactly as prescribed to help lower your chance of getting esophagus problems. (See section 3, “How to take **FOSAVANCE**?”)
- Stop taking **FOSAVANCE** and call your doctor right away if you get chest pain, new or worsening heartburn, or have trouble or pain when you swallow.

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

2. Low calcium levels in your blood (hypocalcemia).

FOSAVANCE may lower the calcium levels in your blood. If you have low blood calcium before you start taking **FOSAVANCE**, it may get worse during treatment. Your low blood calcium must be treated before you take **FOSAVANCE**. Most people with low blood calcium levels do not have symptoms, but some people may have symptoms. Call your doctor right away if you have symptoms of low blood calcium such as:

- Spasms, twitches, 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 take **FOSAVANCE**. Take calcium and vitamin D as your doctor tells you to.

3. Severe bone, joint, or muscle pain.

4. Severe jaw bone problems (osteonecrosis).

Severe jaw bone problems may happen when you take **FOSAVANCE**. Jaw bone problems may include infection and delayed healing after teeth are pulled. Your doctor should examine your mouth before you start **FOSAVANCE**. Your doctor may tell you to see your dentist before you start **FOSAVANCE**. It is important for you to practice good mouth care during treatment with **FOSAVANCE**.

5. Unusual thigh bone fractures.

Some people have developed unusual fractures in their thigh bone. Symptoms of a fracture may 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 (possibly causing difficulty breathing or swallowing) and severe skin reactions.

Call your doctor right away if you have any of these side effects.

The most common side effects of FOSAVANCE are:

- Stomach area (abdominal) pain
- Heartburn
- Constipation
- Diarrhea

- Upset stomach
- Pain in your bones, joints, or muscles
- Nausea

Less common side effects are vomiting, a full or bloated feeling in the stomach, black or bloody stools, gas, itching or eye pain, uveitis (inflammation of the uvea), scleritis (inflammation of the sclera) or episcleritis (inflammation of the episclera), rash that may be made worse by sunlight, hair loss, headache, dizziness, a changed sense of taste, and joint swelling or swelling in the hands or legs.

Other Possible Side Effects:

- Mouth sores (ulcers) may occur if the **FOSAVANCE** tablet is chewed or dissolved in the mouth.
- You may get flu-like symptoms typically at the start of treatment with **FOSAVANCE**.
- 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 appears, if any of the side effects gets serious or if you notice a side effect not mentioned in this leaflet, consult your doctor.

Side effects can be reported to the Ministry of Health by using the link "Adverse Drug Reactions Report" at the home page of the Ministry of Health's web site (www.health.gov.il) which refers to the online side effects reporting form, or by using the link: <https://sideeffects.health.gov.il>

5. HOW TO STORE FOSAVANCE TABLETS?

- Avoid Poisoning! This medicine, as all other medicines, must be stored 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 **FOSAVANCE** after the expiry date (EXP) which is stated on the pack. The expiry date refers to the last day of the indicated month.
- **Storage conditions:** Do not store **FOSAVANCE** above 25°C . Store in the original blister in order to protect from moisture and light.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What FOSAVANCE contains?

- In addition to the active ingredients the medicine also contains inactive ingredients: Microcrystalline cellulose, lactose anhydrous, croscarmellose sodium, magnesium stearate, colloidal silicon dioxide, medium chain triglycerides, butylated hydroxytoluene, sucrose, gelatin, modified food starch, and sodium aluminium silicate.
- **FOSAVANCE** tablets contain lactose and sucrose (see also section 2.7, "**Important information about some of the ingredients of FOSAVANCE**"). Each **FOSAVANCE** tablet contains up to 65.08 mg of lactose anhydrous and up to 17.07 mg sucrose.

What FOSAVANCE looks like and content of the pack

FOSAVANCE tablet is white to off-white, modified rectangular shaped tablet with '270' on one side and a bone shape on the other side.

Pack sizes:

FOSAVANCE pack contains: 2 or 4 tablets per pack.

Not all pack sizes may be marketed.

License holder and address:

Organon Pharma Israel Ltd., 1 Atir Yeda, Kfar Saba

Manufacturer: Organon LLC, NJ USA

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Drug registration no. listed in the official registry of the Ministry of Health:

FOSAVANCE 70 mg/5600 IU TABLETS: 140.99.31792