PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking FOSAVANCE 5600.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- FOSAVANCE 5600 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

FOSAVANCE® 5600 Tablets

1. WHAT FOSAVANCE 5600 CONTAINS

FOSAVANCE 5600 (alendronate sodium/cholecalciferol) are tablets that contain the active ingredients:

- Alendronate monosodium trihydrate which is equivalent to 70 mg alendronic acid (anhydrous free acid) and 140 mcg of cholecalciferol (5600 I.U. of vitamin D_3).

FOSAVANCE 5600 provide a week's supply of vitamin D per tablet.

In addition, FOSAVANCE 5600 contain the following inactive ingredients: Microcrystalline cellulose, lactose anhydrous, medium chain triglycerides, gelatin, croscarmellose sodium,

sucrose, colloidal silicon dioxide, magnesium stearate, butylated hydroxytoluene, modified food starch and sodium aluminium silicate.

Contains lactose and sucrose.

2. WHAT FOSAVANCE 5600 IS USED FOR

The alendronate in FOSAVANCE 5600 is a member of a class of non-hormonal medicines called bisphosphonates. FOSAVANCE 5600 helps to rebuild bone and makes bone less likely to fracture. Vitamin D is an essential nutrient, required for calcium absorption and healthy bones.

Your doctor has prescribed FOSAVANCE 5600 to treat your osteoporosis and to help make sure you get enough vitamin D. This will reduce the risk of developing fractures.

3. BEFORE YOU TAKE FOSAVANCE 5600

Do not take FOSAVANCE 5600 if:

- You are allergic to alendronate or to any of the other ingredients of FOSAVANCE 5600.
- You have certain disorders of the oesophagus (the tube that connects your mouth with your stomach).
- You are unable to stand or sit upright for at least 30 minutes.
- Your doctor has told you that you currently have low blood calcium.
- You are less than 18 years of age (FOSAVANCE 5600 is not indicated for children and should not be given to them).

Take special care with FOSAVANCE 5600

- If you have or have had medical or dental problems, including known kidney disease, and any allergies and if you are or have been a smoker.
- If you have any swallowing or digestive problems. Discuss these with your doctor before taking FOSAVANCE 5600.
- If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking FOSAVANCE 5600 and call your doctor.
- Oesophageal reactions may worsen if patients continue to take FOSAVANCE 5600 after developing symptoms suggesting irritation of the oesophagus.

Pregnancy and Breastfeeding

Do not take FOSAVANCE 5600 if you are pregnant or breastfeeding. If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice, before taking this medicine.

Driving and using machinery

FOSAVANCE 5600 can have side effects which may affect your ability to drive or operate machinery.

Important information about some of the ingredients of FOSAVANCE 5600

FOSAVANCE 5600 contains 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.

Taking other medicine with FOSAVANCE 5600

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

4. HOW TO TAKE FOSAVANCE 5600

Do not share medicines prescribed for you with any other person.

Always take FOSAVANCE 5600 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

These are the important things you must do to help make sure you will benefit from FOSAVANCE 5600:

1. Choose the day of the week that best fits your schedule. Every week, take one FOSAVANCE 5600 tablet on your chosen day.
2. After getting up for the day and before taking your first food, beverage or other medication, swallow your FOSAVANCE 5600 tablet with a full glass (180 to 240 ml) of **plain water** only.

   Do not take FOSAVANCE 5600 with:

   - mineral water
   - coffee or tea
   - juice.

   Do not chew or suck on a tablet of FOSAVANCE 5600.
3. After swallowing your FOSAVANCE 5600 tablet do not lie down - 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.
4. Do not take FOSAVANCE 5600 at bedtime or before getting up for the day.

   The above actions will help the FOSAVANCE 5600 tablet reach your stomach quickly and help reduce the potential for irritation of your oesophagus (the tube that connects your mouth with your stomach).

5. After swallowing your FOSAVANCE 5600 tablet, wait at least 30 minutes before taking your first food, beverage, or other medication of the day, including antacids, calcium supplements and vitamins. FOSAVANCE 5600 is effective only if taken when your stomach is empty.
6. It is important that you continue taking FOSAVANCE 5600 for as long as your doctor prescribes it. FOSAVANCE 5600 can treat your osteoporosis only if you continue to take it.

If you take more FOSAVANCE 5600 than you should:

Drink a full glass of milk and contact your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre. Do not induce vomiting. Do not lie down.

If you miss a dose, just take one FOSAVANCE 5600 tablet on the morning after you remember. *Do not take two tablets on the same day.* Return to taking one tablet once a week, as originally scheduled on your chosen day.

Do not share medicines prescribed for you with others.

5. POSSIBLE SIDE EFFECTS

FOSAVANCE 5600 can have side effects. Not all side effects reported for FOSAVANCE 5600 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Side effects may include digestive disturbances such as nausea, vomiting or black and/or bloody stools. Some digestive disturbances may be severe including irritation or ulceration of

the oesophagus (the tube that connects your mouth with your stomach) which can cause chest pain, heartburn or difficulty or pain upon swallowing. These reactions may occur especially if patients do not drink a **full** glass of water with FOSAVANCE 5600 and/or if they lie down in less than 30 minutes **or** before their first food of the day. Oesophageal reactions may worsen if patients continue to take FOSAVANCE 5600 after developing symptoms suggesting irritation of the oesophagus.

Some patients may experience bone, muscle and/or joint pain, which may be severe. Patients who develop severe bone, joint, and/or muscle pain should contact their doctor. Most patients experienced relief after stopping FOSAVANCE 5600.

You may also experience joint swelling or swelling in your hands or legs. Transient flu-like symptoms (with or without fever), typically at the start of treatment, may occur. Some patients taking FOSAVANCE 5600 may get itching or eye pain, or a rash that may be made worse by sunlight. Hair loss has been reported. Rarely, severe skin reactions may occur. Allergic reactions such as hives or, swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing may occur. Patients may experience dizziness or a changed sense of taste. Stomach or other peptic ulcers (some severe) may occur. Mouth ulcers have occurred when the tablet was chewed or dissolved in the mouth.

Rarely, patients have had jaw problems associated with delayed healing and infection, often following tooth extraction.

Rarely, patients have experienced fracture in a specific part of the thigh bone. If you develop new or unusual pain in the hip or thigh, contact your doctor.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF FOSAVANCE 5600

Do not use this medicine after the month and year following EXP.: on the carton.

Store FOSAVANCE 5600 at or below 25 °C. Protect from moisture and light. Store tablets in the original blister package until use.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION

FOSAVANCE 5600 Tablets will be packaged in push-through aluminium blisters in packs containing 4 tablets.

8. IDENTIFICATION

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

9. REGISTRATION NUMBER

44/3.2/0350

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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