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EPAR summary for the public

Fosavance

alendronic acid and colecalciferol

This is a summary of the European public assessment report (EPAR) for Fosavance. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Fosavance.

What is Fosavance?

Fosavance is a medicine that contains two active substances: alendronic acid and colecalciferol (vitamin D_3). It is available as tablets (70 mg alendronic acid and 2,800 international units [IU] colecalciferol; 70 mg alendronic acid and 5,600 IU colecalciferol).

What is Fosavance used for?

Fosavance (containing either 2,800 or 5,600 IU colecalciferol) is used to treat osteoporosis (a disease that makes bones fragile) in women who have been through the menopause and are at risk of low vitamin D levels. Fosavance 70 mg/5,600 IU is for use in patients who are not taking vitamin D supplements. Fosavance reduces the risk of fractures (broken bones) in the spine and the hip.

The medicine can only be obtained with a prescription.

How is Fosavance used?

The recommended dose of Fosavance is one tablet once a week. It is intended for long-term use.

The patient must take the tablet with a full glass of water (but not mineral water), at least 30 minutes before any food, drink or other medicines (including antacids, calcium supplements and vitamins). To avoid irritation of the oesophagus (the tube that leads from the mouth to the stomach), the patient should not lie down until after their first food of the day, which should be at least 30 minutes after taking the tablet. The tablet should be swallowed whole and not crushed, chewed or allowed to dissolve in the mouth.

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Patients should also take calcium supplements if they are not getting enough calcium from their diet. For more information, see the package leaflet.

How does Fosavance work?

Osteoporosis happens when not enough new bone grows to replace the bone that is naturally broken down. Gradually, the bones become thin and fragile, and more likely to break. Osteoporosis is more common in women after the menopause, when the levels of the female hormone oestrogen fall, since oestrogen helps to keep bones healthy.

Fosavance contains two active substances: alendronic acid and colecalciferol (vitamin D_3). Alendronic acid is a bisphosphonate that has been used for osteoporosis since the mid-1990s. It slows the action of the osteoclasts, the cells that are involved in breaking down the bone tissue. Blocking the action of these cells leads to less bone loss. Vitamin D_3 is a nutrient that is found in some foods, but is also made in the skin through exposure to natural sunlight. Vitamin D_3, along with other forms of vitamin D, is required for calcium absorption and normal bone formation. Since patients with osteoporosis may not get enough vitamin D_3 through exposure to sunlight, it is included in Fosavance.

How has Fosavance been studied?

Because alendronic acid and vitamin D_3 are already used separately in authorised medicines in the European Union (EU), the company presented data obtained in earlier studies and from the published literature from women who had been through the menopause and who were taking alendronic acid and vitamin D as separate tablets.

To support the combination of alendronic acid and vitamin D_3 in the same tablet, the company also carried out a study in 717 patients with osteoporosis, including 682 women who had been through the menopause, to show Fosavance's ability to increase vitamin D levels. Patients received either Fosavance 70 mg/2,800 IU or alendronic acid only once a week. The main measure of effectiveness was the reduction in the number of patients with low vitamin D levels after 15 weeks. This study was extended in 652 patients for a further 24 weeks to compare the effects of continuing with Fosavance 70 mg/2,800 IU on its own or adding another 2,800 IU vitamin D_3 (equivalent to using Fosavance 70 mg/5,600 IU).

What benefit has Fosavance shown during the studies?

The information presented by the company from earlier studies and the published literature showed that the dose of alendronic acid included in Fosavance was the same as the dose needed to prevent bone loss.

The additional studies showed that including vitamin D_3 in the same tablet with alendronic acid could increase vitamin D levels. After 15 weeks, fewer patients had low vitamin D levels when they took Fosavance 70 mg/2,800 IU (11%) than when they took alendronic acid only (32%). In the extension study, similar numbers of patients taking Fosavance 70 mg/2,800 IU and Fosavance 70 mg/5,600 IU had low vitamin D levels (below 6%), but the patients taking Fosavance 70 mg/5,600 IU had greater increases in vitamin D levels over the 24 weeks of the study.

What is the risk associated with Fosavance?

The most common side effects with Fosavance (seen between 1 and 10 patients in 100) are headache, abdominal pain (stomach ache), dyspepsia (heartburn), constipation, diarrhoea, flatulence (gas),

ulcers in the oesophagus, dysphagia (difficulty swallowing), abdominal distension (swollen tummy), acid regurgitation and musculoskeletal pain (pain in the muscles, bones and joints). For the full list of all side effects reported with Fosavance, see the package leaflet.

Fosavance must not be used in patients who have abnormalities of the oesophagus, who have hypocalcaemia (low blood calcium levels), or who cannot stand or sit upright for at least 30 minutes. for the full list of restrictions, see the package leaflet.

Why has Fosavance been approved?

The CHMP decided that Fosavance's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Fosavance?

A risk management plan has been developed to ensure that Fosavance is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Fosavance, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Fosavance:

The European Commission granted a marketing authorisation valid throughout the EU for Fosavance on 24 August 2005.

The full EPAR for Fosavance can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Fosavance, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2015.