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EPAR summary for the public

Vantavo[1]

alendronic acid and colecalciferol

This document is a summary of the European Public Assessment Report (EPAR) for Vantavo. 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 Vantavo.

What is Vantavo?

Vantavo 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 Vantavo used for?

Vantavo (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. Vantavo 70 mg/5,600 IU is for use in patients who are not taking vitamin D supplements. Vantavo reduces the risk of broken bones in the spine and the hip.

The medicine can only be obtained with a prescription.

How is Vantavo used?

The recommended dose 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 (gullet), the patient should not lie down until after their first food of

[1] Previously known as Alendronate Sodium And Colecalciferol, MSD.

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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.

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 Vantavo 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.

Vantavo contains two active substances: alendronic acid and colecalciferol (vitamin D_3). Alendronic acid is a bisphosphonate that has been used in 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 Vantavo.

How has Vantavo been studied?

Because alendronic acid and vitamin D_3 are already used separately in authorised medicines in the 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 Vantavo's ability to increase vitamin D levels. Patients received either Vantavo 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 Vantavo 70 mg/2,800 IU on its own or adding 2,800 IU vitamin D_3 (equivalent to using Vantavo 70 mg/5,600 IU).

What benefit has Vantavo 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 Vantavo 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 Vantavo 70 mg/2,800 IU (11%) than when they took alendronic acid only (32%). In the extension study, similar numbers of patients taking Vantavo 70 mg/2,800 IU and Vantavo 70 mg/5,600 IU had low vitamin D levels (below 6%), but the patients taking Vantavo 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 Vantavo?

The most common side effects with Vantavo include abdominal pain (stomach ache), dyspepsia (heartburn), oesophageal (gullet) ulcers, dysphagia (difficulty swallowing), abdominal distension (swollen tummy) and acid regurgitation. For the full list of all side effects reported with Vantavo, see the package leaflet.

Vantavo 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 Vantavo been approved?

The CHMP decided that Vantavo'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 Vantavo?

A risk management plan has been developed to ensure that Vantavo 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 Vantavo, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Vantavo:

The European Commission granted a marketing authorisation valid throughout the EU for Alendronate Sodium And Colecalciferol, MSD on 16 October 2009. This authorisation was based on the authorisation granted to Fosavance in 2005 ('informed consent'). The name of the medicine was changed to Vantavo on 26 March 2010.

The full EPAR for Vantavo 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 Vantavo, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2014.