LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Actibon
(cholecalciferol, sodium alendronate trihydrate, alendronic acid)

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Tablet, 70 mg/2800 IE, 70 mg/5600 IE

This is a summary of the public assessment report (PAR) for Actibon. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Actibon and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called FOSAVANCE 70 mg/2,800 IU and FOSAVANCE 70 mg/5,600 IU tablets authorised in Union.

The product is used in the treatment of postmenopausal osteoporosis in women at risk of vitamin D insufficiency. It reduces the risk of vertebral and hip fractures.

How does Actibon work?

Alendronate belongs to a group of non-hormonal medicines called bisphosphonates. Alendronate prevents the loss of bone that occurs in women after they have been through the menopause, and helps to rebuild bone. It reduces the risk of spine and hip fractures.
Vitamin D3 is an essential nutrient, required for calcium absorption and healthy bones. The body can only absorb calcium properly from our food if it has enough vitamin D3. Very few foods contain vitamin D3. The main source is through exposure to summer sunlight, which makes vitamin D3 in our skin. As we get older our skin makes less vitamin D3. Too little vitamin D3 may lead to bone loss and osteoporosis. Severe vitamin D3 deficiency may cause muscle weakness which can lead to falls and a greater risk of fractures.
Your doctor has prescribed Actibon to treat your osteoporosis and because you are at risk of vitamin D3 insufficiency. It reduces the risk of spine and hip fractures in women after menopause.

How is Actibon used?

The pharmaceutical form is tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Actibon have been shown in studies?

Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, FOSAVANCE 70 mg/2,800 IU tablets and FOSAVANCE 70 mg/5,600 IU tablets. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Actibon?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Actibon approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for FOSAVANCE 70 mg/2,800 IU tablets and FOSAVANCE 70 mg/5,600 IU tablets, the benefits are greater than its risks and recommended that it can be approved for use.

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

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

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Actibon

The full PAR for Actibon can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Actibon , please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2024-03.