

VI.2 Elements for a Public Summary

[Invented name] 70 mg/ 2800 IU tablets

[Invented name] 70 mg/ 5600 IU tablets

VI.2.1 Overview of disease epidemiology

Osteoporosis

Osteoporosis is a condition which weakens the bones, making them more likely to break. Bone density starts decreasing after approximately 35 years of age. In the first few years after the menopause, women lose bone rapidly. Often, there are no particular symptoms associated with osteoporosis until a minor fall causes a bone fracture. Risk factors other than age include: drinking, smoking, presence of chronic inflammatory disease (e.g. rheumatoid arthritis), family history and long-term use of medication which affects bone strength (e.g. oral prednisolone). It is estimated that over 200 million people worldwide suffer from osteoporosis. Approximately 30% of all postmenopausal women have osteoporosis in the United States and in Europe. Treatment of osteoporosis in postmenopausal women at increased risk of fractures typically includes calcium and vitamin D supplements combined with a bisphosphonate drug, such as risedronic acid (slows down bone loss).

VI.2.2 Summary of treatment benefits

[Invented name] is a tablet containing the two active substances, alendronic acid (commonly called alendronate) and colecalciferol known as vitamin D3.

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 D 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 D. Very few foods contain vitamin D. The main source is through exposure to summer sunlight, which makes vitamin D in our skin. As we get older our skin makes less vitamin D. Too little vitamin D may lead to bone loss and osteoporosis. Severe lack of vitamin D may cause muscle weakness which can lead to falls and a greater risk of fractures.

VI.2.3 Unknowns relating to treatment benefits

The safety and efficacy of alendronic acid/cholecalciferol in children and adolescents below 18 years has not been established.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Irritation of the tube that connects your mouth and your stomach (oesophagus) (Oesophageal adverse experiences)	Irritation or inflammation of the oesophagus (the tube that connects your mouth and your stomach) or stomach can occur uncommonly (up to 1 in 100 people) with [Invented name] use.	Always take this medicine as prescribed by your doctor and as indicated in the Package Leaflet. This will minimise the risk of developing adverse drug reactions. Tell your doctor if you have active upper gastrointestinal

		problems. Stop taking [Invented name] and contact your doctor immediately if you have difficulty swallowing, painful swallowing, pain behind the breastbone, or new or worsening heartburn.
Dead bone tissue in the jaw bone (Osteonecrosis of the jaw)	This side effect may affect up to 1 in 10,000 people. Pain or sore in your mouth or jaw are early signs of severe jaw problems.	A dental examination with appropriate preventive dentistry should be considered prior to treatment, especially if you have the following risk factors: e.g. cancer, chemotherapy, radiotherapy, corticosteroids, poor oral hygiene. If you have one of these risk factors, you should avoid invasive dental procedures if possible while on treatment. If you are having dental treatment or surgery or know that you need some in the future, tell your dentist that you are being treated with [Invented name] >.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Atypical femoral fractures	The long-term use of bisphosphonates is thought to be the main risk factor for atypical femoral fractures. Some patients experience thigh or groin pain, often associated with imaging features of stress fractures, weeks to months before presenting with a completed femoral fracture. During bisphosphonate treatment, you should report any thigh, hip or groin pain.

Missing information

Risk	What is known
Use during Pregnancy and Lactation	[Invented name] is only intended for use in postmenopausal women. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Use in patients below 18 years of age	The safety and efficacy of alendronic acid/cholecalciferol in children and adolescents below 18 years has not been established.
Use in patients with severe renal insufficiency [GFR less than 35 mL/min]	Patients treated with the medicinal product may be at an increased risk of developing kidney problems. There are concerns about using bisphosphonates in patients with existing kidney problems and also in older people.

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

No post-authorisation studies have been imposed or are planned.

VI.2.7 Summary of changes to the Risk Management Plan over time

Not applicable.