

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Vitamin D deficiency

The intended use of Vitamin D capsules is to prevent vitamin D deficiency (in at risk individuals) as well as to treat an existing vitamin D deficiency. Vitamin D deficiency is now widespread worldwide, and has been found in all age groups. Vitamin D deficiency is more likely to occur in certain ethnic groups such as Asians, and African Americans, and is more likely to occur in winter. As the amount of vitamin D occurring in the diet including in fortified foods is insufficient to maintain healthy levels of the vitamin in the body a lack of sufficient exposure to sunshine has been identified as a main cause of the increase in vitamin D deficiency. Low vitamin D levels have been found in 28 to 100% of healthy adults in Europe, and in 70-100% of hospitalized adults.

An adequate calcium intake and adequate amounts of vitamin D are important foundations for maintaining bone density and strength. However, vitamin D and calcium alone are not sufficient treatment for osteoporosis and are given in conjunction with other treatments. A global study showed that almost a quarter of postmenopausal women with osteoporosis had very low levels of vitamin D. This finding was more common in women in central and southern Europe. An estimated 50% of elderly women consume far less vitamin D in their diet than is recommended.

VI.2.2 Summary of treatment benefits

Vitamin D (colcalciferol) is established for the treatment of vitamin D deficiency.

VI.2.3 Unknowns relating to treatment benefits

None identified.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Calcium level in your blood is above normal (hypercalcemia) and / or elevated calcium in the urine (hypercalciuria)	Taking vitamin D can alter your calcium levels.	Do not take this medicine if you have high levels of calcium.
Interactions with drugs such as phenytoin, barbiturates, corticosteroids, rifampicin, isoniazid, some diuretics (water tablets), antacids containing aluminum, digitalis and some other cardiac drugs, cholestyramine, colestipol,	This medication has the potential to interact with a number of other medicinal products resulting in a varying degree of potential complications.	Talk to youDoctor or Phrmacist before taking this medicine is you take any other medicines.

Risk	What is known	Preventability
orlistat, laxatives such as paraffin oil, actinomycin and some antifungal agents		

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Overdose / Hypervitaminosis D	If you have high levels of vitamin D in your body and you take more, the levels will rise.

Important missing information

Risk	What is known
None	

VI.2.5 Summary of risk minimisation measures by safety concern

Not applicable.

VI.2.6 Planned post authorisation development plan

Not applicable.

List of studies in post authorisation development plan

Not applicable.

Studies which are a condition of the marketing authorisation

Not applicable.