Designed for compliance

## Vitamin D Medication

## **ADULT DOSING FREQUENCY** '

Weekly Treatment of vitamin D deficiency 25 (OH) D <25 nmol/l 2 x 25,000 IU capsules weekly for 6 – 8 weeks

Altavita D3 25,000 IU soft capsules Prevention/ Adjunct to osteoporosis treatments 1 x 25,000 IU capsule Monthly



For further information visit altavita.ie



Licensed Medicine for Vitamin D Deficiency Altavita Abbreviated Prescribing Information - for full prescribing information, including side effects, precautions and contra-indications, see Summary of Product Characteristics (SmPC)

Product name and Composition: Altavita D3 25,000 IU soft capsules: each capsule contains 0.625 mg cholecalciferol, equivalent to 25,000 IU vitamin D. Indications: Altavita D3 25,000 IU soft capsules: Treatment and prophylaxis of Vitamin D deficiency in adolescents and adults with an identified risk. As an adjunct to specific therapy for osteoporosis in patients with Vitamin D deficiency or at risk of Vitamin D insufficiency. Dosage and administration: Altavita D3 25,000 IU soft capsules: Children aged 10-18 years: Prevention of deficiency, 25,000 IU (1 capsule) every 6 weeks. Treatment of deficiency, 25,000 IU (1 capsule) once every 2 weeks for 6 weeks followed by maintenance therapy of 400 - 1,000 IU/day, such as 1 capsule per month. Pregnancy and breastfeeding: The high strength formulation is not recommended. Altavita D3 25,000 IU soft capsules Adults: Prevention of deficiency, 25,000 IU/month (1 x 25,000 IU capsule); higher doses and monitoring of serum 25(OH)D may be required in populations at high risk of vitamin D deficiency (\* see below) Adjunct to specific therapy for osteoporosis, 25,000 IU/month (1 x 25,000 IU capsule). Treatment of deficiency (<25 nmol/L), 50,000 IU/ week for 6-8 weeks followed by maintenance therapy 1,400 - 2,000 IU/day, may be required such as 2 x 25,000 IU capsules per month; follow-up 25(OH)D measurements should be made approximately 3-4 months after initiating maintenance therapy to confirm that the target level has been achieved. \*Altavita D3 25,000 IU soft capsules: Special populations: Populations at high risk of vitamin D deficiency include those who are institutionalised or hospitalised, dark skinned, obese, being evaluated for osteoporosis, with limited effective sun exposure due to protective clothing or consistent use of sun screens, using certain concomitant medication e.g. anticonvulsants or glucocorticoids, with malabsorption, including inflammatory bowel disease and coeliac diseasea and recently treated for vitamin D deficiency, and requiring maintenance therapy. Altavita D3 25,000 IU soft capsules should not be used in combination with calcium in patients with severe renal impairment. Administration to Adults: Altavita D3 should be taken orally - the capsules should be swallowed whole with water. Patients should be advised to take Altavita D3 25,000 IU preferably with a meal.

Hypersensitivity to the active substance or to any of the excinients: hypercalcaemia and/or hypercalciuria; nephrolithiasis and/or nephrocalcinosis; hypervitaminosis D. Pregnancy and breastfeeding: Due to lack of clinical data Altavita D3 25,000 IU is not recommended. Warnings and precautions: Altavita D3 soft capsules: Use with caution in impaired renal function. Patients receiving treatment for cardiovascular disease with drugs containing digitalis and other cardiac glycosides plus Vitamin D may increase risk of digitalis toxicity and arrhythmia. Use with caution in patients with sarcoidosis. Allow for the total dose of vitamin D where patients consume treatments and / or foodstuffs enriched with vitamin D and for the patient's level of sun exposure. Possible risk of renal stones especially with concomitant calcium supplementation; consider the need for additional calcium supplementation for individual patients. Calcium supplements should be given under close medical supervision. For a full list of interactions see the full SmPC. Altavita D3 25,000 IU soft capsules contain Allura Red AC (E129). These excipients may cause allergic reactions. Undesirable effects: Altavita D3 soft capsules:Not known (cannot be estimated from the available data): Hypersensitivity reactions such as angio-oedema or laryngeal oedema Uncommon (>1/1,000, <1/100): Hypercalcaemia and hypercalciuria. Rare (>1/10,000, <1/1,000): pruritus, rash, urticaria. Legal Classification all products: POM. MA number: Altavita D3 25,000 IU soft capsules: PA1876/004/0033. Marketing Authorisation Holder: Altavita D3 25,000 IU soft capsules Consilient Health Limited, Floor 3, Block 3, Miesian Plaza, Dublin 2, D02Y754, Ireland. Further information is available on request from Consilient Health Ltd. Block 2A, Richview Office Park, Clonskeagh, Dublin 14 Ireland, 01 2057760 or drugsafety@consilienthealth.com

Contraindications: Altavita D3 25,000 IU soft capsules:

IE-ALT-395(1)

Date of preparation of prescribing information: June 2023

 Healthcare professionals are asked to report any suspected adverse reactions. To report an adverse event or a product complaint about a Consilient Health medicine, please contact Consilient Health at drugsafety@consilienthealth.com or 01 2057766

Adverse events and product complaints may also be reported to the Health Products Regulatory Authority. Reporting forms and information can be found at <u>www.hpra.ie</u> then click on "report an issue".

References

1. Consilient Health Ltd. Altavita® D3 25,000 IU soft capsules, Summary of Product Characteristics - available on medicines.ie.



Your Partner in Bone Health Visit consilienthealth.ie

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