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 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 capsule). *Treatment of deficiency (<25 nmol/L),* 50,000 IU/week (2 capsules) for 6-8 weeks followed by maintenance therapy 1,400 – 2,000 IU/day, may be required such as 2 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:** 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 disease and recently treated for vitamin D deficiency, and requiring maintenance therapy. Special populations: **Altavita D3 25,000 IU** 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. **Contraindications: Altavita D3 25,000 IU soft capsules:** Hypersensitivity to the active substance or to any of the excipients; 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:** Use with caution in impaired renal function; monitor effect on calcium and phosphate levels. Consider the risk of soft tissue calcification. Exercise caution in patients receiving treatment for cardiovascular disease as concomitant administration of vitamin D with drugs containing digitalis and other cardiac glycosides may increase risk of digitalis toxicity and arrhythmia; strict medical supervision is needed, with serum calcium concentration and electrocardiographic monitoring if necessary. Use with caution in patients with sarcoidosis due to possible increase in vitamin D metabolism; monitor serum and urinary calcium levels in these patients. 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). **Undesirable effects:** *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:** POM. **MT number: MA1490/00102. Marketing Authorisation Holder:** Consilient Health Limited, Floor 3, Block 3, Miesian Plaza, Dublin 2, D02 Y754, 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.

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- **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 00353 1 2057766**
- **Adverse events and product complaints may also be reported to the Health Products Regulatory Authority. Reporting forms and information can be found at** www.hpra.ie **then click on "report an issue".**