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 1,000 IU soft capsules. Each capsule contains 1,000 IU colecalciferol (equivalent to 0.025 mg vitamin D3), **Altavita D3 7,000 IU soft capsules.** Each capsule contains 7,000 IU colecalciferol (equivalent to 0.175 mg vitamin D3). **Altavita D3 25,000 IU soft capsules & Altavita D3 25,000 IU oral solution:** each capsule or single dose oral solution contains 0.625 mg cholecalciferol, equivalent to 25,000 IU vitamin **D. Altavita D3 50,000 IU**, equivalent to 1.25 mg cholecalciferol. **Indications: Altavita D3 50,000 soft capsules:** Treatment of Vitamin D deficiency, **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. **Altavita D3 25,000 IU oral solution:** Prevention and treatment of Vitamin D deficiency. As an adjunct to specific therapy for osteoporosis in patients with Vitamin D deficiency or at risk of Vitamin D insufficiency. **Altavita D3 1,000 IU soft capsules and Altavita D3 7,000 IU soft capsules:** Prophylaxis and treatment of vitamin D deficiency in children, adolescents and adults with an identified risk. Prophylaxis of vitamin D deficiency in pregnant and breast-feeding women with an identified risk. As an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D deficiency. **Dosage and administration: Altavita D3 1,000 IU soft capsules** are suitable for daily supplementation. **Paediatric posology:**
Doses of up to 1,000 IU/day may be required to prevent deficiency in some children. Treatment of deficiency 10-18 years 2,000 IU/day for 6 weeks, followed by maintenance therapy of 400-1,000 IU/day (such as one 1,000 IU soft capsule per day or one 7,000 IU soft capsule per week). **Pregnancy and breastfeeding:** Doses of 1,000 – 2,000 IU/day may be required to prevent deficiency in some women. **Adults:** Prevention of vitamin D deficiency: 1,000 IU/day**.** As an a*djunct to specific therapy for osteoporosis:* 1,000 IU/day. *Treatment of deficiency*: 1,000 IU – 4,000 IU/day for up to 12 weeks, followed by maintenance therapy of 1,400 – 2,000 IU/day (such as two 1,000 IU soft capsules per day) **Altavita D3 7,000 IU soft capsules:** Suitable for weekly supplementation, which should be taken into consideration and dosage should be established by a physician. The dose of 1,000 IU/day is considered equivalent to 7,000 IU/week. Pregnancy and breastfeeding: Doses of 1,000 – 2,000 IU/day may be required to prevent deficiency in some women (see below). Even higher doses may be required during breast-feeding if women choose not to give the infant a vitamin D supplement. Adults - *prevention of vitamin D deficiency* 1,000 IU/day.As an a*djunct to specific therapy for osteoporosis:* 1,000 IU/day. *Treatment of deficiency*: 1,000 IU – 4,000 IU/day for up to 12 weeks, followed by maintenance therapy of 1,400 – 2,000 IU/day, such as two 7,000 IU soft capsules per week). **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 Altavita D3 50,000 IU** (only indicated for Vitamin D deficiency): *Prevention of deficiency*, 25,000 IU/month (1 capsule or single dose oral solution); 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 or single dose oral solution). *Treatment of deficiency (<25 nmol/L),* 50,000 IU/week (2 capsules or single dose oral solution) for 6-8 weeks followed by maintenance therapy 1,400 – 2,000 IU/day, may be required such as 2 capsules or oral solutions 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 25,000 IU oral solution**: Paediatric posology: *Prevention of deficiency 0-1 years* 25000 IU (1 single dose oral solution) every 8 weeks, *Prevention of deficiency 1-18 years* 25,000 IU (1 single dose oral solution) every 6 weeks. *Treatment of deficiency* 0-18 years 25,000 IU (1 single dose oral solution) once every 2 weeks for 6 weeks, followed by maintenance therapy of 400 -1000 IU/day (such as 1 25,000 IU single dose oral solution per month). ***Altavita D3 1,000 & 7,000 IU soft capsules , Altavita D3 25,000 IU soft capsules, Altavita D3 50,000 IU & Altavita 25,000 IU oral solution:** 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, Altavita D3 50,000 IU soft capsules and oral solution** 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, for **the oral solution** the full contents of the single dose oral solution should be either emptied into the mouth and swallowed orally, or emptied onto a spoon and taken orally. AltavitaD3 can also be taken by mixing with a small amount of cold or lukewarm food immediately prior to use. Patients should be advised to take Altavita D3 25,000 IU preferably with a meal. Administration to children: In children, **Altavita D3** oral solution can be mixed with a small amount of children's foods, yogurt, milk, cheese or other dairy products. Parents should be warned not to mix

Altavita D3 oral solution into a bottle of milk or container of soft foods in case the child does not consume the whole portion, and does not receive the full dose. They should ensure that their child takes the entire dose. For children who are not being breast-fed, the prescribed dose should be administered with a meal. **Contraindications: Altavita D3 1,000 IU soft capsules, Altavita D3 7,000 IU soft capsules, Altavita D3 25,000 IU, Altavita D3 50,000 IU soft capsules, & AltaVita 25,000 IU oral solution:** 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. **Altavita D3 50,000 IU** is contraindicated in Pregnancy and Children and Adolescents under the age of 18 years. **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 1,000 IU soft capsules, 25,000 IU** and **Altavita D3 50,000 soft capsules** contain Allura Red AC (E129). **Altavita D3 7,000 IU soft capsules** contain Sunset Yellow FCF (E110). These excipients may cause allergic reactions. **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. **Price**: https:// www.consilienthealth.ie/our-medicines/pricing-of-our-medicines/ **Legal Classification:** POM. **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. Job Bag Code**:** IE-ALT-230(4). **Date of preparation of prescribing information:** March 2026.

- **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** www.hpra.ie **then click on "report an issue".**