InVitaD3 (colecalciferol) Abbreviated Prescribing Information - for full prescribing information, including side effects, precautions and contra-indications, see Summaries of Product Characteristics (SmPC).

Product name and Composition: InVita D3 50,000 IU oral solution: 1 ml solution (1 single-dose oral solution) contains 1.25 mg colecalciferol, equivalent to 50,000 IU vitamin D3. **InVita D3 50,000 IU soft capsules**: each capsule contains 50,000 IU colecalciferol, equivalent to 1.25 mg vitamin D3. **InVita D3 25,000 IU oral solution:** 1 ml solution (1 single-dose oral solution) contains 0.625 mg cholecalciferol, equivalent to 25,000 IU vitamin D. **InVita D3 25,000 IU soft capsules:** each capsule contains 25,000 IU colecalciferol, equivalent to 0.625 mg vitamin D3. **InVita D3 5,600 IU soft capsules:** each capsule contains colecalciferol 5,600 IU, equivalent to 0.14 mg vitamin D3. **InVita D3 2,400 IU/ml oral drops, solution:** 1 ml solution (36 drops) contains 0.06 mg colecalciferol, equivalent to 2,400 IU vitamin D3. **InVita D3 800 IU soft capsules:** each capsule contains colecalciferol 800 IU (equivalent to 0.02 mg vitamin D3. **InVita D3 400 IU soft capsules:** each capsule contains 400 IU colecalciferol, equivalent to 0.01 mg vitamin D3. **Indications: InVita D3 50,000 IU oral solution, InVita D3 50,000 IU soft capsules:** The treatment of vitamin D deficiency. **InVita D3 25,000 IU oral solution:** The 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. **InVita D3 25,000 IU soft capsules:** Prophylaxis and treatment of vitamin D deficiency in adults and adolescents 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. **InVita D3 5,600 IU soft capsules:** Prophylaxis and treatment of vitamin D deficiency in adults and adolescents with an identified risk. As an adjunct to specific therapy for osteoporosis in patients at risk of vitamin D deficiency, preferably in combination with calcium. **InVita D3 2,400 IU/ml oral drops, solution:** Prevention of vitamin D deficiency in infants and children. Prevention of vitamin D deficiency in pregnant and breast-feeding women. **InVita D3 800 IU soft capsules:** Prophylaxis and treatment of vitamin D deficiency in adults and adolescents with an identified risk. As an adjunct to specific therapy for osteoporosis in patients at risk of vitamin D deficiency, preferably in combination with calcium. **InVita D3 400 IU soft capsules:** Prophylaxis and treatment of vitamin D deficiency in children and adolescents with an identified risk. Prophylaxis of vitamin D deficiency in adults, 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: InVita D3 50,000 IU oral solution, InVita D3 50,000 IU soft capsules:** Infants and children: Due to a lack of clinical data, not recommended in the paediatric population. Pregnancy and breastfeeding: Due to a lack of clinical data, not recommended. Adults: 50,000 IU/week (1 single-dose oral solution or 1 capsule) for 6-8 weeks, followed by maintenance therapy (equivalent to 1400-2000 IU/day, such as 1 single-dose 50,000 IU oral solution or capsule per month) may be required; check 25(OH)D measurements 3-4 months after starting maintenance therapy. Higher doses and monitoring of serum 25(OH)D may be required in populations at high risk of vitamin D deficiency (including 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). Renal impairment: should not be used in combination with calcium in patients with severe renal impairment. Take orally, preferably with food, capsules swallowed whole and oral solution either directly or by mixing with a small amount of cold or lukewarm food or drink immediately prior to use. **InVita D3 25,000 IU oral solution, InVita D3 25,000 IU soft capsules:** Infants and children: *Prevention of deficiency*, 0-1 year 25000 IU (1 single-dose oral solution) every 8 weeks; 1-18 years 25000 IU (1 single-dose oral solution) every 6 weeks; 10-18 years 25000 IU (1 capsule) every 6 weeks. *Treatment of deficiency*, 0-18 years 25000 IU (1 single-dose oral solution) once every 2 weeks for 6 weeks followed by maintenance therapy of 400-1000 IU/day such as 25000 IU (1 single-dose oral solution) per month; 10-18 years 25000 IU (1 capsule) every 2 weeks for 6 weeks followed by maintenance therapy of 400 – 1000 IU per day such as 25000 IU (1 capsule) per month. Pregnancy and breastfeeding: not recommended. Adults: *Prevention of deficiency*, 25000 IU (1 single-dose oral solution or capsule) per month; higher doses and monitoring of serum 25(OH)D may be required in populations at high risk of vitamin D deficiency (including 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). *Adjunct to specific therapy for osteoporosis*, 25000 IU (1 single-dose oral solution) per month. *Treatment of vitamin D deficiency (<25 ng/ml)*, 50000 IU/week (2 single-dose oral solutions or 2 capsules) for 6-8 weeks, followed by maintenance therapy of 1400-2000 IU/day such as 50000 IU (2 single-dose oral solutions or 2 capsules) per month may be required; check 25(OH)D measurements 3-4 months after starting maintenance therapy). Renal impairment: InVita D3 should not be used in combination with calcium in patients with severe renal impairment. **InVita D3 5,600 IU soft capsules:** One capsule per week; increase if necessary to achieve desirable serum levels of 25-hydroxycolecalciferol (25(OH)D). The weekly dose should not exceed 5 capsules. Renal impairment: InVita D3 should not be used in patients with severe renal impairment. Paediatric population: InVita D3 is not recommended in children under 12 years of age. The capsules should be swallowed whole with water. **InVita D3 2,400 IU/ml oral drops, solution:** Infants and Children: Age 0-1 years 400 IU/day (6 drops); Age 1-18 years 600 IU/day (9 drops). Pregnancy and breastfeeding: 400 IU/day (6 drops). Special populations renal impairment: no specific adjustment required. Obese patients, patients with malabsorption syndromes, and patients on medications affecting vitamin D metabolism: higher doses are required for the treatment and prevention of vitamin D deficiency (2-3 times higher). Take InVita D3 orally, preferably with food, either directly or by mixing with a small amount of cold or lukewarm food immediately prior to use. Ensure that the entire dose is taken. For children who are not breastfeeding, the prescribed dose should be administered with a meal. **InVita D3 800 IU soft capsules:** One capsule (800 IU) per day; increase if necessary for treatment of vitamin D deficiency, with dose adjusted according to desirable serum levels of 25-hydroxycolecalciferol (25(OH)D), the severity of the disease and the patient's response to treatment. The daily dose should not exceed 4,000 IU (5 capsules per day). Renal impairment: Do not use in patients with severe renal impairment. Paediatric population: Not recommended in children under 12 years of age. The capsules should be swallowed whole with water. **InVita D3 400 IU soft capsules:** Paediatric: *Prevention of deficiency, 10-18 years* 800 IU/day (2 capsules); increase to maximum 1200 IU/day (3 capsules) if required. *Treatment of deficiency, 10-18 years* 2000 IU/day (5 capsules) for 6 weeks, followed by maintenance therapy of 400-1200 IU/day (1-3 capsules). Pregnancy and breastfeeding: *Prevention of deficiency*, 400 IU/day (1 capsule); increase up to 2000 IU/day (5 capsules) if required. Even higher doses may be required during breast-feeding if women choose not to give the infant a vitamin D3 supplement. Adults: *Prevention of deficiency,* 800 IU/day (2 capsules); higher doses and monitoring of serum 25(OH)D may be required in populations at high risk of vitamin D deficiency (including 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). *Adjunct to specific therapy for osteoporosis,* 800 IU/day (2 capsules). Take InVita D3 orally with water, preferably with food. **Contraindications: InVita D3 50,000 IU oral solution, InVita D3 50,000 IU soft capsules, InVita D3 25,000 IU oral solution, InVita D3 25,000 IU soft capsules, InVita D3 400 IU soft capsules:** Hypersensitivity to the active substance or to any of the excipients; hypercalcaemia and/or hypercalciuria; nephrolithiasis and/or nephrocalcinosis; serious renal impairment; hypervitaminosis D; pseudohypoparathyroidism; InVita D3 25,000 IU soft capsules only, pregnancy. **InVita D3 5,600 IU soft capsules, InVita D3 800 IU soft capsules:** Hypersensitivity to the active substance or to any of the excipients; hypercalcaemia and/or hypercalciuria; nephrolithiasis and/ or nephrocalcinosis; hypervitaminosis D. **InVita D3 2,400 IU/ml oral drops, solution:** Hypersensitivity to the active substance or to any of the excipients; hypercalcaemia and/or hypercalciuria; hypervitaminosis D; kidney stones (nephrolithiasis, nephrocalcinosis) in patients with current chronic hypercalcaemia. **Warnings and precautions: InVita D3 50,000 IU oral solution, InVita D3 50,000 IU soft capsules, InVita D3 25,000 IU oral solution, InVita D3 25,000 IU soft capsules, InVita D3 400 IU soft capsules:** 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. **InVita D3 5,600 IU soft capsules, InVita D3 800 IU soft capsules:** Use with caution in impaired renal function; monitor effect on calcium and phosphate levels. Consider the risk of soft tissue calcification. In patients with severe renal insufficiency, colecalciferol is not metabolised normally and other forms of vitamin D should be used. During long-term treatment, monitor serum calcium levels and renal function (via serum creatinine measurements). Monitoring is especially important in elderly patients on concomitant treatment with cardiac glycosides or diuretics and in patients with a high tendency to calculus formation. In case of hypercalciuria (exceeding 300 mg (7.5 mmol)/24 hours) or signs of impaired renal function the dose should be reduced or the treatment discontinued. 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 containing vitamin D. Additional doses of vitamin D should be taken under close medical supervision; monitor serum calcium levels and urinary calcium excretion frequently. InVita D3 5,600 IU soft capsules contain Allura Red AC (E129) and Sunset Yellow FCF (E110) which may cause allergic reactions. **Undesirable effects:** All presentations: *Uncommon (>1/1,000, <1/100):* Hypercalcaemia and hypercalciuria. *Rare (>1/10,000, <1/1,000):* pruritus, rash, urticaria. **Additionally, for InVita D3 5,600 IU soft capsules, InVita D3 800 IU soft capsules:** *Not known (cannot be estimated from the available data):* Hypersensitivity reactions such as angio-oedema or laryngeal oedema. **NHS Price**: **InVita D3 50,000 IU oral solution:** £6.25 per pack of 3 x 1ml ampoules. **InVita D3 50,000 IU soft capsules:** £4.95 per pack of 3 capsules. **InVita D3 25,000 IU oral solution:** £4.45 per pack of 3 x 1ml ampoules. **InVita D3 25,000 IU soft capsules:** £3.95 per pack of 3 capsules. **InVita D3 5,600 IU soft capsules**: £2.50 per pack of 4 capsules. **InVita D3 2,400 IU/ml oral drops, solution:** £3.60 per 10ml bottle. **InVita D3 800 IU soft capsules:** £2.50 per pack of 28 capsules. **InVita D3 400 IU soft capsules:** £1.85 per pack of 28 tablets. **Legal Classification:** POM. **MA number: InVita D3 50,000 IU oral solution:** PL 24837/0076. **InVita D3 50,000 IU soft capsules:** PL 24837/0074**. InVita D3 25,000 IU oral solution:** PL 24837/0039. **InVita D3 25,000 IU soft capsules:** PL 24837/0073. **InVita D3 5,600 IU soft capsules:** PL 24837/0077. **InVita D3 2,400 IU/ml oral drops, solution:** PL 24837/0046. **InVita D3 800 IU soft capsules:** PL 24837/0070. **InVita D3 400 IU soft capsules:** PL 24837/0069. **Marketing Authorisation Holder:** Consilient Health Limited, 5th Floor, Beaux Lane House, Mercer Street Lower, Dublin 2, Ireland. Further information is available on request from Consilient Health (UK) Ltd, 1 Church Road, Richmond upon Thames, Surrey, TW9 2QE or drugsafety@consilienthealth.com. **Job Code**: UK-INV-270. **Date of preparation or last revision of PI:** June 2021.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Consilient Health (UK) Ltd, Ground Floor, No. 1 Church Road, Richmond upon Thames, Surrey TW9 2QE UK or drugsafety@consilienthealth.com or on +44(0)203 751 1882