calci-D

calcium carbonate/colecalciferol
1000 mg/1000 IU chewable tablet

Calci-D (calcium carbonate/colecalciferol) Abbreviated Prescribing Information – for full prescribing information, including side effects, precautions and contra- indications, see Summary of Product Characteristics (SPC).

Product name: CALCI-D 1000 mg /1000 IU chewable tablets. **Composition:** One tablet contains 2500 mg calcium carbonate (equivalent to 1000 mg calcium) and 1000 IU colecalciferol (vitamin D3) (equivalent to 0.025 mg). **Indications:** Correction of calcium and vitamin D deficiency in the elderly. As an adjunct to specific therapy for osteoporosis, in patients with either established vitamin D and calcium combined deficiencies or in those patients at high risk of needing such therapeutic supplements. **Dosage and administration:** Adults and elderly: 1 tablet/day chewed or sucked; not swallowed whole. Paediatric population: No relevant use. Pregnant women: One half- tablet a day (see SPC). Hepatic dysfunction: No dosage adjustment required. Renal dysfunction: Should not be used in severe renal dysfunction. **Contraindications:** Hypersensitivity to active substances or excipients; hypercalcaemia (›10.5 mg/dl), hypercalciuria (300 mg or 7.5 mmol/24 hours), severe renal insufficiency, nephrolithiasis, nephrocalcinosus, calcification of tissues, diseases and/or conditions resulting in hypercalciurea and/or hypercalcaemia; hypervitaminosis D. **Warnings and precautions:** During long term treatment monitor serum and urinary calcium levels and kidney function. Monitor in elderly patients on cardiac glycosides or diuretics. Reduce or interrupt treatment in hypercalcaemia, signs of impaired renal function, reduce dose or interrupt treatment or if urinary calcium exceeds 7.5 mmol/24 h (300 mg/24 h). Consider dose of vitamin D when prescribing drugs or food supplements containing vitamin D and give under medical supervision with regular monitoring of plasma and urinary calcium levels. Vitamin D3 may increase the magnitude of hypercalcaemia and/or hypercalciuria in diseases associated with unregulated overproduction of calcitriol (e.g. leukaemia, lymphoma, sarcoidosis); prescribe with caution and monitor urine and serum calcium. Renal insufficiency disturbs vitamin D metabolism; if treated with colecalciferol, the effect on calcium and phosphate homeostasis should be monitored. Risk of soft tissue calcification should be taken into account. Patients with malabsorption may not adequately absorb vitamin D. Use with caution in immobilised patients with osteoporosis due to the increased risk of hypercalcaemia; stop treatment in prolonged immobilisation and only restart after mobility regained. Contains sucrose and isomalt (isomaltitol, E953); patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take Calci-D. May be harmful to teeth. **Undesirable effects:** Uncommon (≥1/1,000, <1/100): Hypercalcaemia, hypercalciuria. Rare (≥1/10,000, <1/1,000): Constipation, flatulence, nausea, stomach pain, diarrhoea, pruritus, rash, urticaria. Not *known (cannot be estimated from available data):* Serious allergic (hypersensitivity) reactions such as angioedema or laryngeal oedema; hyperphosphatemia, nephrolithiasis. **NHS Price:** £2.25 per pack of 28 tablets. **Legal Classification:** P license. **MA number:** PL 24837/0075. **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, No.1 Church Road, Richmond upon Thames, Surrey. TW9 2QE or drugsafety@consilienthealth.com. **Job Code:** UK-CAD-214(1). **Date of preparation of PI:** April 2022.

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, No. 1 Church Road, Richmond upon Thames, Surrey TW9 2QE UK or drugsafety@consilienthealth.com

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