

theiCal-D3® 1000 mg/880 IU chewable tablets – Abbreviated Prescribing Information

Please refer to the appropriate Summary of Product Characteristics (SmPC) before prescribing theiCal-D3® chewable tablets.

Each chewable tablet contains 2,500 mg of calcium carbonate equivalent to 1,000 mg of calcium and 8.8 mg of colecalciferol concentrate equivalent to 880 IU with aspartame (E951), sorbitol (E420), isomalt (E953) and sucrose as excipients. **Indications:** For the prevention and treatment of vitamin D and calcium deficiency in the elderly. Also as an adjunct to specific osteoporosis treatment of adults who are at risk of vitamin D and calcium deficiency. **Dosage and administration:** In adults and the elderly one chewable tablet daily. Tablets are for oral use and should be chewed and then swallowed with or without food. theiCal-D3® should not be used in patients with severe renal impairment. **Pregnancy and lactation:** The daily dose in pregnancy must not exceed half a tablet. Calcium and vitamin D pass into breast milk and this should be taken into consideration when giving additional vitamin D to the child. **Contraindications:** Severe renal impairment, hypercalciuria, hypercalcaemia and any diseases and/or conditions, which lead to hypercalcaemia and/or hypercalciuria (e.g. myeloma, bone metastases, primary hyperparathyroidism, prolonged immobilisation accompanied by hypercalciuria and/or hypercalcaemia). Nephrolithiasis, nephrocalcinosis, hypervitaminosis D. Hypersensitivity to the active substances or to any of the excipients. **Warnings and precautions:** During long-term treatment serum calcium levels should be monitored and renal function should be checked by measuring serum creatinine. Monitoring is especially important in patients taking concomitant cardiac glycosides or thiazide diuretics and in patients with a high tendency to form calculi. In cases of severe renal impairment colecalciferol is not metabolised normally and other forms of vitamin D must be used. Use with caution in patients suffering from sarcoidosis. theiCal-D3® may be harmful for people with phenylketonuria and should not be administered to patients with fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency. **Interactions:** Thiazide diuretics increase the risk of hypercalcaemia which can increase the toxicity of cardiac glycosides. Phenytoin or barbiturates may decrease the effect of vitamin D. Administration of resins such as cholestyramine or paraffin-based laxatives may reduce the absorption of vitamin D. Oxalic acid (found in spinach and rhubarb) and phytic acid (found in cereals) can inhibit calcium absorption. The patient should avoid taking calcium products within two hours of eating foods high in oxalic acid and phytic acid. Calcium carbonate may impair the absorption of tetracyclines and quinolone antibiotics. Administration of calcium and levothyroxine should be at least four hours apart. If a bisphosphonate or sodium fluoride is being taken concomitantly then this must be taken at least three hours before theiCal-D3® 1000 mg/880 IU chewable tablet. Further details on drug interactions can be found in the SmPC. **Adverse effects:** affecting at least 1/1000 but < 1/100 – hypercalcaemia, hypercalciuria, affecting at least 1/10 000 but < 1/1000 – nausea, diarrhoea, abdominal pain, constipation, flatulence, abdominal distension, rash, pruritus, urticaria, cannot be estimated – hypersensitivity reactions. **Overdose:** Refer to the SmPC for detailed advice. **Legal category:** P **Pack size:** 30 chewable tablets in strips of laminated aluminium paper foil. **Shelf life:** 2 years. **NHS price:** 30 chewable tablets = £3.95

Marketing Authorisation Holder: Stirling Anglian Pharmaceuticals Ltd, Hillington Park Innovation Centre, 1 Ainslie Road, Hillington Park, Glasgow G52 4RU **Marketing Authorisation Number:** PL 42582/0014. Further information is available at medinfo@stirlinganglianpharmaceuticals.com or **0330 1359 499**

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Adverse events should be reported. Reporting forms and information can be found at <http://yellowcard.mhra.gov.uk> or downloaded from Google Play or the Apple App store. Adverse events should also be reported to Stirling Anglian Pharmaceuticals on 0330 1359 499 or by emailing medinfo@stirlinganglianpharmaceuticals.com