Abbreviated Prescribing Information

Accrete®-D3
Calcium/Colecalciferol

Accrete D3 One-a-Day 1000 mg/880 IU Chewable Tablets® & Accrete D3 Film-Coated Tablets®

Abbreviated Prescribing Information

Please refer to the appropriate Summary of Product Characteristics (SmPC) before prescribing Accrete D3.

Accrete D3 One-a-Day 1000 mg/880 IU Chewable Tablets®: Each chewable tablet contains 1000 mg calcium (as 2500 mg calcium carbonate) and 880 IU colecalciferol. Contains aspartame (E951), sorbitol (E420), isomalt (E953) and sucrose.

Accrete D3 Film-Coated Tablets®: Contains 600 mg calcium (as calcium carbonate 1500 mg) and 10 micrograms of colecalciferol (equivalent to 400 IU vitamin D3) and sucrose.

Indication: Prevention and treatment of vitamin D and calcium deficiency in the elderly. Adjunct to specific osteoporosis treatment of patients at risk of vitamin D and calcium deficiency.

Dosage and Administration: For oral use. ***Accrete D3 One-a-Day:*** One chewable tablet daily. ***Accrete D3 Film-Coated:*** One tablet twice per day.

Contraindications: Hypersensitivity to any of the ingredients, hypercalciuria/ hypercalcaemia and conditions leading to hypercalciuria/ hypercalcaemia, nephrolithiasis, nephrocalcinosis, hypervitaminosis D, severe renal impairment/ renal failure. Not for paediatric use.

Warnings and Precautions: Monitor serum calcium and creatinine (renal function) in cases of long-term use, concomitant use of cardiac glycosides or thiazide diuretics, or a high tendency to calculus formation. Use caution and monitor calcium and phosphate in cases of renal impairment. In cases of hypercalcaemia or impaired renal function, reduce the dose or discontinue treatment. Use caution in cases of sarcoidosis, immobilised patients with osteoporosis. In patients with a history of renal stones, hypercalciuria should be excluded. Use close medical supervision if prescribing additional calcium or vitamin D via other medicines. Concomitant use of tetracyclines or quinolones is not recommended. Do not take in case of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.This medicinal product contains aspartame (E951), a source of phenylalanine which may be harmful for people with phenylketonuria

Interactions: Thiazide diuretics, cardiac glycosides, systemic corticosteroids, phenytoin, barbiturates, ion exchange resins, laxatives. Do not take calcium within 2 hours of eating foods high in oxalic acid and phytic acid. Administer tetracycline <2 hours before or 4 to 6 hours after Accrete D3. Administer bisphosphonate or sodium fluoride at least 3 hours before Accrete D3. Do not use levothyroxine within 4 hours before or after Accrete D3. Administer quinolone antibiotics <2 hours before or 6 hours after Accrete D3.

Pregnancy and Lactation: During pregnancy, daily dose should not exceed 1500 mg calcium and 600 IU vitamin D. Halve tablet if necessary to reduce dose. Suitable for use during breastfeeding. Calcium and vitamin D pass into breast milk. This should be considered when giving additional vitamin D to the child.

Undesirable effects: Allergic reactions may be possible. Uncommonly hypercalcaemia or hypercalciuria. Rarely gastro-intestinal disorders, rash, pruritus, urticaria.

Legal Category:
Accrete D3 One-a-Day: P;
Accrete D3 Film-Coated: P.

Pack size:
Accrete D3 One-a-Day: £2.95 for 30 tablets;
Accrete D3 Film-Coated: £2.95 for 60 tablets.

MA Number:
Accrete D3 One-a-Day: PL04416/1318;
Accrete D3 Film-Coated: PL 40861/0001

Distributor (Accrete One-a-Day)/MA Holder (Accrete D3 Film-Coated): Internis Pharmaceuticals Ltd., Linthwaite Laboratories, Linthwaite, Huddersfield, HD7 5QH, UK

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Unique ID: ACCR-40

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 Thornton and Ross Limited by emailing thorntonross@medinformation.co.uk or by calling 01484 848164.