#### Calcium Ascorbate (BANM, rINNM)

Ascorbate de Calcium; Ascorbato cálcico; Askorban vápenatý dihydrát; Calcii ascorbas; Calcii Ascorbas Dihydricus; Calcium, ascorbate de; E302; Kalcio askorbatas; Kalciumaskorbat; Kalciumaszkorbát; Kalsiumaskorbaatti.

Кальций Аскорбат  $(C_6H_7O_6)_2Ca,2H_2O=426.3.$  CAS — 5743-27-1.

Pharmacopoeias. In Chin., Eur. (see p.vii), and US.

Ph. Eur. 6.2 (Calcium Ascorbate). A white or slightly yellowish crystalline powder. Freely soluble in water; practically insoluble in alcohol. A 10% solution in water has a pH between 6.8 and 7.4. Store in nonmetallic containers. Protect from light.

**USP 31** (Calcium Ascorbate). A white to slightly yellow, practically odourless, powder. Freely soluble in water (about 1 in 2); slightly soluble in alcohol; insoluble in ether. pH of a 10% solution in water is between 6.8 and 7.4. Store in airtight containers. Protect from light.

#### Sodium Ascorbate (BANM, rINN)

Ascorbate de sodium; Ascorbate sodique; Ascorbato de sodio; Askorban sodný; E301; Monosodium L-Ascorbate; Natrii ascorbas; Natrio askorbatas; Natriumaskorbati; Natriumaskorbat; Nátrium-aszkorbát. 3-Охо-L-gulofuranolactone sodium enolate. Натрия Аскорбат

 $C_6H_7NaO_6 = 198.1.$ CAS — 134-03-2.

Pharmacopoeias. In Chin., Eur. (see p.vii), and US.

Ph. Eur. 6.2 (Sodium Ascorbate). A white or yellowish crystal-line powder or crystals. Freely soluble in water; sparingly soluble in alcohol; practically insoluble in dichoromethane. A 10% solution in water has a pH of 7.0 to 8.0. Store in nonmetallic containers. Protect from light.

**USP 31** (Sodium Ascorbate). White or very faintly yellow, odourless or practically odourless, crystals or crystalline powder. On exposure to light it gradually darkens. Soluble 1 in 1.3 of water; very slightly soluble in alcohol; insoluble in chloroform and in ether. pH of a 10% solution in water is between 7.0 and 8.0. Store in airtight containers. Protect from light.

### **Adverse Effects and Precautions**

Ascorbic acid is usually well tolerated. Large doses are reported to cause diarrhoea and other gastrointestinal disturbances. It has also been stated that large doses may result in hyperoxaluria and the formation of renal calcium oxalate calculi and ascorbic acid should therefore be given with care to patients with hyperoxaluria (see Effects on the Kidneys, below). Tolerance may be induced with prolonged use of large doses, resulting in symptoms of deficiency when intake is reduced to normal. Prolonged or excessive use of chewable vitamin C preparations may cause erosion of tooth enamel.

Large doses of ascorbic acid have resulted in haemolysis in patients with G6PD deficiency (see Effects on the Blood, below).

**Breast feeding.** Vitamin C is excreted into breast milk and thus supplied to breast-feeding infants. Lactating women in developing countries have significantly lower concentrations of ascorbic acid in their breast milk compared with lactating women in developed countries,1 and seasonal variation in consumption of foods rich in vitamin C leads to variable amounts of ascorbic acid in breast milk.<sup>2</sup> Supplementation with high-dose ascorbic acid (1 g daily for 10 days) led to significant increases in breast-milk concentrations in both European and African women;1 however, the overall effect was modest in European women compared with a threefold increase observed in African women. Lower doses of 100 mg daily for 10 days approximately doubled the ascorbic acid breast milk content in the latter, as did supplementation with orange juice 3 or 5 times a week; a significant day-today effect was also noted, indicating that the ascorbic acid content of breast milk is regulated. In a small study2 involving four different doses of ascorbic acid supplements, women in West Africa showed that increased intake caused an increase in the ascorbate concentration of breast milk, but concentrations approached a plateau at higher intakes; it was concluded that about 100 to 120 mg of vitamin C daily was needed to achieve acceptable plasma and breast-milk ascorbate concentrations in this popula-

- Daneel-Otterbech S, et al. Ascorbic acid supplementation and regular consumption of fresh orange juice increase the ascorbic acid content of human milk: studies in European and African lactating women. Am J Clin Nutr 2005; 81: 1088–93.
  Bates CJ, et al. The effect of vitamin C supplementation on lac-
- Bates CJ, et al. The effect of vitamin C supplementation on lactating women in Keneba, a West African rural community. Int J Vitam Nutr Res 1983; 53: 68–76.

**Effects on the blood.** There are reports of haemolysis in patients with G6PD deficiency after large doses of ascorbic acid either intravenously <sup>1,2</sup> or in soft drinks. <sup>3</sup> There has also been a report <sup>4</sup> of a patient with paroxysmal nocturnal haemoglobinuria suffering haemolysis after taking large amounts of ascorbic acid

in a soft drink. There is concern that the large quantities of vitamin C in feeds for premature neonates may have a pro-oxidant effect, and lead to haemolysis. However, a double-blind study found no increase in erythrocyte destruction or hyperbilirubinaemia in premature neonates receiving vitamin C.<sup>5</sup>

- Campbell GD, et al. Ascorbic acid-induced hemolysis in G-6-PD deficiency. Ann Intern Med 1975; 82: 810.
- Rees DC, et al. Acute haemolysis induced by high dose ascorbic acid in glucose-6-phosphate dehydrogenase deficiency. BMJ 1993; 306: 841–2.
- Mehta JB, et al. Ascorbic-acid-induced haemolysis in G-6-PD deficiency. Lancet 1990; 336: 944.
- Iwamoto N, et al. Haemolysis induced by ascorbic acid in paroxysmal nocturnal haemoglobinuria. Lancet 1994; 343: 357.
- Doyle J, et al. Does vitamin C cause hemolysis in premature newborn infants? Results of a multicenter double-blind, randomized, controlled trial. J Pediatr 1997; 130: 103–9.

Effects on the kidneys. Although renal impairment associated with excessive oxalate excretion has been reported with large doses of ascorbic acid<sup>1-3</sup> it has been considered that healthy persons can ingest large amounts of ascorbic acid with relatively small increases in oxalate excretion<sup>4-6</sup> and without an increased risk of oxalate stone formation. A study of vitamin C supplementation with 1 or 2 g given daily for 3 days in calcium stone-forming patients, and 1 g given daily for 3 days in healthy subjects, found that urinary oxalate excretion and the risk of calcium oxalate crystallisation increased significantly in all groups.7 A prospective cohort study found that increased vitamin C intake (over 1 g daily) was positively associated with the risk of stone formation; an increased risk was observed even at lower intakes of about 90 to 250 mg daily. The risk was raised for both dietary and supplemental vitamin C intake. However, the relation between vitamin C intake and stone formation had emerged only after the inclusion of dietary potassium in the analysis, with potassium intake positively associated with dietary vitamin C intake, but inversely associated with stone formation. This led the authors to conclude that, while limiting dietary vitamin C intake in men with calcium oxalate nephrolithiasis was unwarranted (because of the high potassium content of vitamin C-rich foods), supplemental vitamin C should be avoided.8

- Reznik VM, et al. Does high-dose ascorbic acid accelerate renal failure? N Engl J Med 1980; 302: 1418–19.
- Swartz RD, et al. Hyperoxaluria and renal insufficiency due to ascorbic acid administration during total parenteral nutrition. Ann Intern Med 1984: 100: 530-1.
- 3. Balcke P, et al. Ascorbic acid aggravates secondary hyperoxalemia in patients on chronic hemodialysis. Ann Intern Med 1984; 101: 344–5.
- Tsao CS. Ascorbic acid administration and urinary oxalate. Ann Intern Med 1984; 101: 405–6.
- Wandzilak TR, et al. Effect of high dose vitamin C on urinary oxalate levels. J Urol (Baltimore) 1994; 151: 834–7.
- Curhan GC, et al. Intake of vitamins B6 and C and the risk of kidney stones in women. J Am Soc Nephrol 1999; 10: 840–5.
- Baxmann AC, et al. Effect of vitamin C supplements on urinary oxalate and pH in calcium stone-forming patients. Kidney Int 2003; 63: 1066–71.
- Taylor EN, et al. Dietary factors and the risk of incident kidney stones in men: new insights after 14 years of follow-up. J Am Soc Nephrol 2004; 15: 3225–32.

Effects on mortality. There is some suggestion that serum ascorbic acid concentrations are inversely related to all-cause mortality; <sup>1-4</sup> serum levels were also inversely related to cancer mortality in men but not in women. <sup>1-3</sup> However, a meta-analysis of 3 studies found vitamin C supplementation to have no benefit on mortality in elderly people. <sup>3</sup> A systematic review of antoxidant supplementation in adults also found no significant effect on mortality from studies in which vitamin C was used either singly or with other antoxidants; <sup>6</sup> small beneficial effects or large harmful effects could not be excluded, and since vitamin C can also act as a pro-oxidant, further studies should monitor closely for any harm.

- Loria CM, et al. Vitamin C status and mortality in US adults. Am J Clin Nutr 2000; 72: 139–45.
- Simon JA, et al. Relation of serum ascorbic acid to mortality among US adults. J Am Coll Nutr 2001; 20: 255–63.
- Khaw K-T, et al. Relation between plasma ascorbic acid and mortality in men and women in EPIC-Norfolk prospective study: a prospective population study. Lancet 2001; 357: 657–63.
- Fletcher AE, et al. Antioxidant vitamins and mortality in older persons: findings from the nutrition add-on study to the Medical Research Council Trial of Assessment and Management of Older People in the Community. Am J Clin Nutr 2003; 78: 999–1010.
- Ness A, et al. Role of antioxidant vitamins in prevention of cardiovascular diseases. BMJ 1999; 319: 577.
- Bjelakovic G, et al. Antioxidant supplements for prevention of mortality in healthy participants and patients with various diseases. Available in The Cochrane Database of Systematic Reviews; Issue 2. Chichester: John Wiley; 2008 (accessed 18/06/08).

**Effects on the teeth.** A report of dental enamel erosion attributed to the daily ingestion of chewable ascorbic acid tablets over a period of 3 years. The tablets lowered the pH of the saliva to a level at which calcium was lost from the tooth enamel.

 Giunta JL. Dental erosion resulting from chewable vitamin C tablets. J Am Dent Assoc 1983; 107: 253–6. Interference with laboratory tests. Ascorbic acid, a strong reducing agent, interferes with laboratory tests involving oxidation and reduction reactions. Falsely-elevated or false-negative test results may be obtained from plasma, faeces, or urine samples depending on such factors as the dose of ascorbic acid and specific method used.

#### **Interactions**

For the effect of ascorbic acid on various drugs see under desferrioxamine (p.1440), hormonal contraceptives (p.2068), HRT (p.2076), fluphenazine (under Chlorpromazine, p.975), and warfarin (p.1432). Ascorbic acid may increase the absorption of iron in rion-deficiency states. Omeprazole may affect the bioavailability of dietary vitamin C (see Malabsorption, under Omeprazole, p.1754).

#### **Pharmacokinetics**

Ascorbic acid is readily absorbed from the gastrointestinal tract and is widely distributed in the body tissues. Plasma concentrations of ascorbic acid rise as the dose ingested is increased until a plateau is reached with doses of about 90 to 150 mg daily. Body stores of ascorbic acid in health are about 1.5 g although more may be stored at intakes above 200 mg daily. The concentration is higher in leucocytes and platelets than in erythrocytes and plasma. In deficiency states the concentration in leucocytes declines later and at a slower rate, and has been considered to be a better criterion for the evaluation of deficiency than the concentration in plasma.

Ascorbic acid is reversibly oxidised to dehydroascorbic acid; some is metabolised to ascorbate-2-sulfate, which is inactive, and oxalic acid which are excreted in the urine. Ascorbic acid in excess of the body's needs is also rapidly eliminated unchanged in the urine; this generally occurs with intakes exceeding 100 mg daily. Ascorbic acid crosses the placenta and is distributed into breast milk. It is removed by haemodialysis.

## **Human Requirements**

A daily dietary intake of about 30 to 100 mg of vitamin C has been recommended for adults. There is, however, wide variation in individual requirements. Humans are unable to form their own ascorbic acid and so a dietary source is necessary. Most dietary ascorbic acid is obtained from fruit and vegetable sources; only small amounts are present in milk and animal tissues. Relatively rich sources include rose hips (rose fruit), black currant, citrus fruits, leafy vegetables, tomatoes, potatoes, and green and red peppers.

Ascorbic acid is readily destroyed during cooking processes. Considerable losses may also occur during storage.

UK and US recommended dietary intake. In the UK¹ dietary reference values (see p.1925) have been published for vitamin C and similarly in the USA recommended dietary allowances (RDAs) have been set.² Differing amounts are recommended for infants and children of varying ages, for adult males and females, and for pregnant and lactating women. In the UK the reference nutrient intake (RNI) is 40 mg daily for adult males and females and the estimated average requirement (EAR) is 30 mg daily. In general the amount recommended in the USA for all ages and groups is higher than that set in the UK; the RDA is 90 mg daily for men and 75 mg daily for women.² The RDA is increased in smokers by 35 mg daily. The tolerable upper intake level is 2 g daily.² The EAR is 75 mg daily for men and 60 mg daily for women.

- DoH. Dietary reference values for food energy and nutrients for the United Kingdom: report of the panel on dietary reference values of the committee on medical aspects of food policy. Report on health and social subjects 41. London: HMSO, 1991.
- Standing Committee on the Scientific Evaluation of Dietary Reference ence Intakes of the Food and Nutrition Board. Dietary Reference Intakes for vitamin C, vitamin E, selenium, and carotenoids. Washington DC: National Academy Press, 2000. Also available at: http://www.nap.edu/openbook.php?isbn=0309069351 (accessed 21,077,08)

### **Uses and Administration**

Vitamin C, a water-soluble vitamin, is essential for the synthesis of collagen and intercellular material. Vitamin C deficiency develops when the dietary intake is inadequate. It is rare in adults, but may occur in infants, alcoholics, or the elderly. Deficiency leads to the devel-

opment of a well-defined syndrome known as scurvy. This is characterised by capillary fragility, bleeding (especially from small blood vessels and the gums), normocytic or macrocytic anaemia, cartilage and bone lesions, and slow healing of wounds.

Vitamin C is used in the treatment and prevention of deficiency. It completely reverses symptoms of deficiency. It is usually given orally, the preferred route, as ascorbic acid, and has been given to children in the form of a suitable fruit juice such as orange juice or as black currant or rose hip syrups. Ascorbic acid or sodium ascorbate may be given parenterally, preferably by the intramuscular route, but also by the intravenous or subcutaneous routes. Doses of 25 to 75 mg daily in the prevention of deficiency, and 250 mg or more daily in divided doses for the treatment of deficiency, have

Ascorbic acid 100 to 200 mg daily may be given with desferrioxamine in the treatment of patients with thalassaemia, to improve the chelating action of desferrioxamine, thereby increasing the excretion of iron (see p.1441). In iron deficiency states ascorbic acid may increase gastrointestinal iron absorption and ascorbic acid or ascorbate salts are therefore included in some oral iron preparations. Ascorbic acid or sodium ascorbate have been used in treating methaemoglobinaemia. Ascorbic acid has been used to acidify urine. It has also been tried in the treatment of many other disorders (see below) but there is little evidence of beneficial effect.

Eye drops containing potassium ascorbate (ascorbic acid 10%) have been used for the treatment of chemical eye burns (p.1674); they may be used with sodium citrate eye drops (see Uses of Bicarbonate, p.1674).

Ascorbic acid and calcium and sodium ascorbates are used as antoxidants in pharmaceutical manufacturing and in the food industry.

Non-deficiency disorders. A beneficial effect of vitamin C therapy has been claimed for an extraordinary number of conditions, including age-related macular degeneration (under Betacarotene, p.1931) Alzheimer's disease (see Dementia, under Vitamin E, p.1994), atherosclerosis (see Prophylaxis of Ischaemic Heart Disease, p.1926), cancer (see Prophylaxis of Malignant Neoplasms, p.1927), the common cold (p.850), and idiopathic thrombocytopenic purpura (p.1505). Other conditions claimed to benefit include asthma, wound healing, psychiatric disorders, infections due to abnormal leucocyte function, infertility, osteo-genesis imperfecta, pain in Paget's disease, and opioid withdrawal. Generally there are few properly controlled studies to substantiate these claims. Although preliminary evidence suggested a benefit in pre-eclampsia, this was not confirmed in later studies (see Hypertension, p.1171).

# **Preparations**

BP 2008: Ascorbic Acid Injection; Ascorbic Acid Tablets; Paediatric Vitamins A, C and D Oral Drops; Vitamins B and C Injection; USP 31: Ascorbic Acid Injection; Ascorbic Acid Oral Solution; Ascorbic

### Proprietary Preparations (details are given in Part 3)

Arg.: Cebion†; Cellskinlab Serum 15; Cewin; Citrocola; Citrovita; Gynefix; Arg.: Cebion†; Cellskinlab Serum 15; Cewin; Citrocola; Citrovita; Gynefix, Redoxon; Urosedac; Vicenrik; Vitafizz C; Austral.: Bioglan Cal C; Pro-C†; Redoxon; Sugarless C; Supa C†; Vicks Vital†; Vita C†; Austria: Ascorbin; C-Vit; Calcascorbin; Ce-Limo; Cebion; Cetebe; Cevitol; Iroviton Vitamin C; Iroviton-Irovovit-C†; Mel-C; Redoxon; Upsa C; Upsavit C; Braz.: Active C; Bio-C; Cebion; Ceklin†; Cenevit; Cetivit Cetozone; Cevita; Ceviton; Cewin; Citrovit; Cetoxon; Vagid; C; Vi-Ce; Vitabase Vitamina C†; Vitacitrus†; Vitageyer C†; Vitamice; Vitergy C; Canad.: Action; Ascorbex†; Balanced C Complex†; Ester-C; Kamu Jay†; Kyolic Formula 103; Nutrol C; Proflavanol C; Redoxon; Revitalose C†; Revitonus C; Super C; Vita-C†; Chile: Cebion; Crevet; Crevet; L; Esvit C; Mintanic; C; Neta C; Redoxon; Vitac; Vita-C†; Chile: Cebion; Crevet; Crevet; C; Fr.: Arkoviton; Cebion†; Celaskon; Linamon†; Fin.: Ascorbin; Bio-C-Vitamin; C-Tabs; C-Vitarin; Cevi-Tabs; Poremax-C; Puru-C; Vita-C; Fr.: Arkoviton; Midy Vitamine C; Vita-Crobolo; Ger.: Ascoreli; min; Gebont; Celaskon; Linamont; Pini. Ascoroin; Biol-C-vinami; C-laskon; Linamont; Pini. Ascoroin; Geerevain; Cevi-Labs; Poremax-C; Puru-C; Vita-C; Fr.: Arkovital C; Doliactic: Laroscorbine; Midy Vitamine C; Vitascorbol; Ger.: Ascoroli; Ascorvit, C-190†; Cebion; Cebion N†; Cetebe; Forum C; Hermes Cevitt; Macalvit; Synum C†; Vagi-C; Gr.: Ascorbine†; Cebion†; Vitorange; Hong Kong; Cecap; Cegrovit; Celin†; Cetrinets; Champs Junior; Delrosa; Flavettes; Redoxon; Vicenev; Vorange; Hung.: Beres C; Cebion; Cetebe; Hermes Cevitt; Vitascor; India: Cecon; Celin; Limcee; Sukcee; Indon.: Askorbin; Bekamin C; Biferer; Cebion; Champs C; Ever Ce; Extrace; Fit-C; Flavettes; Sweeta C; Vicce; Vitacimin; Vitalong C TRC; Vitamex C; Xon-Ce; Ind.: Addivita; Agrurnin; Agruvit; Bio-C; C Monovit; C-Lisa†; C-Tard; Cebion; Cimille; Duo-C; Dynaphos-C; Grumivit†; Redoxon; Univit; Vic; Ipn: Hicee; Malaysia: Ascorbin; Cecap; Ceelin; Cetrinest†; Chewette C; Citrex Vitamin C; Dumovit C†; Orange C†; Upha C; Vita C; Mex.: Ce-Vi-Sol; Cemina†; Cevalin; Dermoskin C†; Femiprim; Gomas Garde G; Oxital C; Roy C; Redoxon; Rosenin; Neth.: C-Vill; Dayvital; Redoxon; Norw: Bio-C; Nycoplus C-vitamin; NZ: Citravite†; Redoxon; Philipp:: Ascorovita; Ascorce; Bonalet-Cee; C-4-Kids; Calcebone; CareZee; Ce-Vi-Sol;

Cecon; Ceelin; Cetrasol; Cetrinets; Chilcee; Chilvit-Cee; Cixtor; Daycee; Esvicee; Incee-Vit; Nutricee; Pedcee; Pediafortan-C; Poten-Cee; Provit-Cee; Supravit-C; Vamcee; Zerrucee; Pol.: Ascorgem; Cebion; Cetebe; Cevikap; Supravit-C; Vamcee; Zerrucee; Pol.: Ascorgem; Cebion; Cetebe; Cevikap; Juvit; Monovitan C; Vicefar; Port.: Anti-rugas C; Chorgi; Cebiolon; Cebi-on; Cecon; Cecnisna; Cetebe†; Citavi†; Prevegyne†; Redoxon; Vitaminac, Retard; Vivin C; Rus.: Celascon (Целаскон); Citravi (Цигравит); Plivit С (Пивит С)†; S.Afr.: Chewy С†; Rovit С†; Scorbex; Vitaforce C; Vitaforce Massif-C; Singapore: Active C; Ascorbin; Cebion; Cetrinets†; Champs C; Dancimin-C; Dumovit C†; Flavettes; High-C; Redoxon; Vorange; Spain: Cebion; Citrovit; Redoxon; Unimicebrina†; Swed.: C-vimin; Ido-C; Switz.: Cegrovit†; Cetebe; Demovit C; Neutra-C†; Nicobrevin N†; Redoxon Vicemex†; Viforcit†; Vita-Ce†; **Thai.**: Bio-C; C Mon†; C-Will; Hicee; Med-Vicemex†; Viforcit†; Vita-Ce C; Mita-C; Sweetcee; Teddy-C; Mita-C; Sweetcee; Teddy-C†; Vit C-Mile; Vitacinin; Turk:: C-plan; Ester Vit; Redoxon; Vitabiol C; UK: Buffered C; Buffered C 500; Haliborange Halibonbons; Redoxon; USA: Asco-Caps; Ascocid, Ascor; Cecon; Cenolate; Cev-Bid; Chew-C; Dull-C; Nice Vitamin C; Sunkist; Vita-C; Venez.: Cebion; Cevax; Cevit; Mirinda†; Oranvit†; Redoxon†; Vitadyn C; Vitrexon.

Multi-ingredient: Arg.: A-D-C; Ajo 1000 + C; Ajo Forte; Ascoxal†; Aseptobron Antigripal; Bayaspirina C; Bio Grip D; Bio Grip Plus; Bio-Grip C; Calcium C; Cardiax; Cellskinlab C + AHA; Cellskinlab C + E; Citrovita; Coriovaccine; Corizina; Corvita C; CVP B1 B6 B12†; CVP Duo; CVP Flebo; novaccine; Corizina; Corvita C; CVP B1 B B12;†; CVP Diuto; CVP Fleeto; Cyclo 3; Daygip; Dristan Analgesico;†, Dristan Compuesto; Epiteliol-C; Expectosan Hierbas y Miel; Factus; Fiblast; Finagrip†; Flucalin; Fullgrip; Gripanil C; Inmunogrip C; IP-6; Isalax Fibras; Kacerutin; Mejoral Grip T Descongestivo; Melagel; Mudagrip†; Nectar G; Nervigenol Magnesio†; Nilflux; Nulagrip C†; Parageniol Grip Callente; Parencias†; Pirinace; Potasio C; Provacsin Oral; Redoxon A; Redoxon Doble Accion; Rumisedan; Sigma C; Provacsin Oral; Redoxon A; Redoxon Doble Accion; Rumisedar, Sigma CE: Sigmace Plus, Uridon; Venart; Vendium; Venter; Viclor Gnj; Vita-C Dermss; Wilpan Antigripal; Wilpan C†; Austral.: Action Cold & Flu; Anthogenol; Antioxidant Forte Tablets; Antioxidant Tablets; Ascoxal; Beta Ac Q; Bio C; Bio Magnesium; Bio-C Complex; Bioglan Cirflo†; Bioglan Mega C; Bioglan Super Cal C; Bioglan Zn-A-C; C Supa + Bioflavonoids†; Cold & Flu Tablets Non Drowsy; Cold and Flu Relief†; Cold Sore Relief†; Cranberry Complex; Echinacea 4000; Echinacea Lozenge; Extralife Leg-Care; Extralife Uri-Care; Eye Health Herbal Plus Formula 4; Flavons, Garlic and Horseradish + C Complex; Garlic, Horseradish, A & C Capsules†; Gentle C with Bioflavonoids†; Glycoprep-C; Hair and Skin Formula†; Infant Tonic†; Ironto-Biollavonoids†; Glycoprep-C; Hair and Skin Formula†; Infant Tonic†; Ironto-na; Lifesystem Herbal Plus Formula 5 Eye Relief†; Lifesystem Herbal Plus Formula 8 Echinacea†; Logicin Natural Lozenges†; Macro C†; Neo-C; Pro-cold†; Proyeast†; Redoxon Double Strength; Slow Release Mega C†; Sore Throat Chewing Gum†; Strepsils Zinc Cold Relief; Super Cal-C Bio; Sus-tained Release C; Verbascum Complex†; Vitatona; Zinc + C250†; Zinc C Plus†; Zinc Zenith; Zinvit C; Austria: Ado C; Adolorin ASS/H C; Adoquick Vt C; Ascorbisa; Aspirin + C; Aspro mit Vitamin C; ASS + C; ASS plus Vit C; Calcipot C; Calcisan B + C; Calcisan C; Ce-Limo-Calcium; Cebion plus Rutin; Grippinon; Grippostad C; Helopyrin; Iromin-Chinin-C; Lemazol; Macalvit; Mexa-Vit C; Neo Citran; Nisicur; Ossiplex; Phlebodril; Ruticalzon; calvit, Mexa-Vit C.; Neo Citran; Nisicur; Ossiplex; Phiebodnii; Ruticaizon; Rutiscorbini; Seltoc; Tetesept; Thomapynin mit Vitamin C; Timedil (Ultren; ViCetamol; Vit-C-Lutsch; Waldheim Influvidon; Belg.: Afebryl; Aspirine C; Efferalgan C†; Guronsan; Medica Junior; Perdognip; Perdolan Mono C†; Redoxon + Zink; Sandoz Calcium + Vitamine C†; Sedergine C†; Strepsils Vit C; Braz.: Algice; Amigdalol; Analgin C-R; Aspirina C; Baldin-CE†; Biofrut†; Bromii; Broncopinol†; Calcium-Sandoz + Vitamina C; Castanha de India Composta†; Cebion Calcio; Cebion Plus Com Minerais†; Cebion Plus Magnesio†; Cebion Zinco; Coldrin; Coquevit†; Dactil OB; Dinavital C; Euraginesio ; Ceolio Zinco; Colini; Codjevri; Datur Ox, Dillaviai C; Dillaviai C; Caliptant; Folacin; Forgript; Ginglione; Gripanit†; Gripcaps C†; Gripen; Gripen F; Griponit†; Griponia†; Gripsay; Griptol†; Killgrip†; Lima C; Limao Bravo com Vitamina C†; Limao Bravo†; Melhoral C†; Nogripe; Pulmorien†; Redoxon Zinco; Resfry; Resprax; Suprasten†; Targifor C; Termogripe C†; Trimedal; Vick Pyrena; Vita Grip; Vitercal C; Canad.: Citron Chaud DM; Cran-C†; Hot Lemon; Hot Lemon Relief; Hot Lemon Relief for Cough and Cold; Neo Citran A†; Neo Citran†; One A Day Cold Season†; Cough and Colin, Neo Cital m., Callon, Neo Cital m., Neo C na; Tapsin Compuesto Dia/Noche Plus; Tapsin Compuesto DN; Tapsin Limonada DN; Tapsin Limonada Dia†; Tapsin Limonada Noche†; Trio-D†; Cz.: Acylpyrin + C; Ascorutin; Aspirin C; Aspro C†; Calcium C Neo; D†: **Cz.:** Acylpyin + C.: Ascorutin: Aspirin C.: Aspro C†: Calcium Č Neo; Calcium C†: Cemaquin†; Coldrex, Coldrex Hotrem; Coldrex MaxGrip; Cyclo 3 Fort: Efferalgan Vitamin C; Febrisan; Fervex; Grippostad C; Grippostad Horky Napo; Magnesium Pharmavit; Mexavit; Ossiplex†; Paraskorbin†; Redoxon Double Action; Rhinoval Cf.; Rign Nţ†: Strepsils Vitamin C; Tetesept Angidin†: Tomapyrin Cţ†: Tirgip; Upsarin C; **Fin.:** Ascoxal†; Aspirin C; Burana-C; Cellavie†; Coldrex; Finrexin; Posinova; Posivil†; **Fr.:** Acti 5; Adena Cţ\*; Afebrylţ\*; Aphtoral: Ascortory); Aspirine vitamine C; Aspro vitamine C; Bicirkan; Broncorinol maux de gorgeţ\*; Ca-Cţ\*; Catalgine Vitamine Cţ\*; Edeuloy; Cirkan; Codetricine vitamine Cţ\*; Cyclo 3 Fort; Detoxalgineţ\*; Efferalgan Vitamine C; Fastenyl; Fervex; Guronsan; Humex Mal de Gorge sans sucre; Moviprep; Nicoprive; Ophtadilţ\*; Phakanţ\*; Revitalose; Rhinofebral; Sargenor a la Vitamine C; Strepsils Vitamine C; Tonicalcium; Vascocitrol; Velnobiase; Velnostase; Venylţ\*; Vitathion; **Ger.:** Aspirin plus C; ASS + C; Boxazin plus C; Cebion Erkaltungş\*; Ferro-C-Calcium; Fibrex Hot itrol, ventoblase, venioslase, veninji, vitatilori, **ven:** Aspirin plus C., Caso, C.; Boxazin plus C.; Cebion Erkaltungs†; Ferro-C-Calcium; Fibrac Hot Drink†; Fornagrippin N†; Grippostad C.; Jasimenth CN; NeyDop N. (Revitorgan-Dilutionen N Nr 97)†; NeyPulpin N. (Revitorgan-Dilutionen N nr 97)†; NeyPulpin N.; Ruticalzon VC†; Thomapyrin C.; Togal Kopfschmerzbrause + Vitamin C; Tyrosolvetten-C†; Vitamin C-Calci-Togal Kopfschmerzbrause + Vitamin G, Tyrosolvetten-C†, Vitamin C-Calcium†; Wick Daymed Erkaltungs; Gr.: Apotel C-500, Aspin C; Cyclo 3 Forte; Depon-Vitt. C; flavobion-C; Gluta-calcium†; Panadol+C; Salospir C-500, Hong Kong; Beechams Hot Lemon†; Ca-C†; Callimon; Cemaquin†, Coldrex†, Havo-C; Lemspiţ†, Neozep; Panadol Cold & Flu Day, Panadol Cold & Flu Day, Panadol Cold & Flu Day, Panadol Cold and Flu; Phenahist; Poly C†; Pregnacare; Procosamine†; Proflavanol†; Redoxon Double Action; Vitacimin Sweetlet; Welsan Lipocream; Hung; Aspirin plus C; Aspro C; ASS + C; Blackcurrant Coldrex Hot†; Calcium-Sandoz + Vitamin C; Coldrex; Coldrex MaxGrip; Efferalgan C†; Fervex Grippostad C; Lemon Coldrex; Magnezium†; Neo Citran; Ossiplex†; Rhinoval C†; Rutascorbin; Strepsils Vitamin C; Upsarin C†; ViCetamol; Vitacalc†; India: Cadisper C; Citravite; CKP; CVP, Fervit†; Gynae-CVP; Hepasules; Kalpastic; Livogen†; Siochrome; Styptocid; Styptocip†; Indon.: Agrippin; Aptivim Optimum Joint Formula; Calcium-Sandoz Vit C; Champs C with Usine; Decolgen; Deprex; Flutamol; Jointfit; Juvelon-C; Matase; Neozep, Phenadex, Proza; Redoxon Double Action; Sentril; Stamino; StarMuno; Stop Cold; Vitaslim; Int.: Beechams Flut-Plus†; Beechams Hot Lemon Decongestant†; Froza, Redoxon Double Action; sentin; satmin, satmin, stap Coin; stap Coin, s Benagol Vitamina C; Bronchenolo Antiflu; Capill; Centella Complex; Coryfin C; Ecamannan; Efferalgan C; Epargriseovit; Idro P2†; Idroskin C; Influ-Zinc;

Influvit; Istantal; Jodo Calcio Vitaminico; Levital Plus; Lipaven; Neo Borocillina

C; Neo Uniplus C†; Neomyrt Plus; Ossiplex†; Raffreddoremed; Rubjovit; Rutisan CE†; Salicina; Sargenor Plus; Sinegrip; Tachiflu; Tachifludec; Varicofit; Vivin C; Zerinoflu; **Malaysia**: Calcium-Sandoz + Vitarnin C; Chitosan C†† Nat-C; Proflavanol, Time Release Nutrition Mega B + C Complex; Vitarnin C-500 YSP, **Mex.**: Actiman; Adekon C; Ascoxal; C-1000-C; Cal-Rutina; Clorfriol†; Fabroven; Flavit; Gripaleta†; Guayalin-Plus†; Noxvid; Nutrem; Pharbrix; Proflavanol; Rosavit C; Vidamil; Vitanumonyl C; **Neth.**: Aflukin C; Antigrippine; Aspirine C; Buckleys Kinderhoestsiroop; Citrosan; Finimal C; Hot Coldrex; Strepsils Sinaasappel en Vitamine C; Norw.: Ascoxal†; NZ: Botanica Hayfever; Lemsip Flu Strength; Redoxon Double Action; Strepsils Echinacea Defence; Strepsils with Vitamin C; Strepsils Zinc Defence; **Philipp.:** Bo-D-Fense; Delrosa; Liposorb; Osteo-4; Pynocare 40 Actisome; Time-Cee; **Pol.:** Apap C Plus, Ascalcin Plus, Ascorutical, Aspirin C, Bioaron C, Biovision; Calcium 500D; Calcium C, Calcium-Sandoz + Vitamin C, Cerutin; Coldrex HotRem; Coldrex MaxGrip; Coldrex MaxGrip C; Cyclo 3 Fort; Efferalgan Vitamin C; Effervit Calcium; Febrisan; Fervex; Grippostad Grypostop Mix; MaxFlu; Polopiryna C; Rutinacea; Rutinoscorbin; Rutokal C; Rutovit C; Scorbolamid; Sebidin; Tetesept; Tiliros; Troxescorbin; Upsarin C; V-piryna; **Port.**: Afebryl; Aspirina C; Ca-C; Cegripe; Codiasp; Cortigripe; Cyclo 3; Gripetral; Guronsan; Ilvico N; Lipoforte†; Medifon; Paramolan C; Cyclo 3; Gripetral; Guronsan; Ilvico N; Lipoforte†; Medifon; Paramolan С; Phakan†; Rinogan†; Rutinice Fortissimo; Rus.: Antigrippin-ANVI (Антигриппин-АНВИ); Ascorutical (Аскорутикаль); Aspirin С (Аспирин-С); Coldrex HotRem Lemon (Колдрекс ХотРем со Вкусом Лимона); Coldrex MaxGrip Lemon (Колдрекс МаксПриппо со Вкусом Лимона); Cyclo 3 Fort (Цикло-3 Форт); Daleron С (Далерон С); Grippostad (Гриппостад); Grippostad С (Гриппостад); Grippostad С (Гриппостад); Crippostad С (Гриппостад); Стророван С (Гриппостад); Стророван С (Припостад); Максикола); Мехамит (Мексавит); Midol С (Мидол С); Paracetamol-C (Парацетамол-С); Prosetadatic (Провышения С Scheling); Собышь 1 Травър В. Въвера С С (Педавт), Ностания С (Пидок ), На всеменно С (Паравсе намоче), По-риуасти С (Профилактин С); Sebidin (Себидин); TheraFlu Flu and Cold (ТераФлю от Гриппа и Простуды Экстра); Vectrum Calcium (Вектрум Кальций); **S.Afr.:** Borstol Cold and Flu Powders with Vitamin C; Colcaps; Coldvico; Colstat; Corenza C; Coryx; Degoran C; Endcol Cold & Flu; Expectotussin C†; Famucaps; Flu-Stat; Flusin C; Flusin DM; Flusin S; Flutex; Flutex Cold and Flu; Grippon; Histamed Compound; Ilvico; Med-Lemon Hot Medication with Vitamin C; Med-Lemon Hot Medication-Lemon Menthol; Merck-Flu; Nitroflu†; Ossiplex; Panado Medsip; Paracetacod; Sandoz Calcium-C†; Strepsils Orange-C; Vitaplus C Plus; **Singapore**: Ca-C; Carti-pro; Champs C with Lysine; Cyclo 3 Fort; Febs; Flexeze†; Memoloba†; Papro, Champs C with Estine, Cyclo 3 rot i; etcs, riexeze; i rierrioloda; i radol Cold & Rlu Hot Remedy, Poly C; Proflavanol, Proza; Redoxon All Day Defence; Redoxon Double Action; **Spain**: Acyflox, Aftasone B C; Alergical; Algidol, Aspirina C; Beecham Lemon; Calcio 20 Complex; Calmagrip; Carnante Vitaminado PG Efervescente; Clamarvit; Cortafriol C; Couldina C; Desenfriol C; Dolmen; Efferalgan Vit C; Fabroven; Fluxalf; Frenadol Complex; Gingilone; Gramoce A; Guronsan; Lema C; Odontocromil c Sulfamida†; Pastillas Antisep Garg L; Propalgina Plus; Redoxon Calciovit; Rimagrip; Rinomicine; Sedergine C; Strepsils con Vitamina C; Vicomin A C; Nariagrip, Nilotinie, Becelgine C, Stepanie Con Vitalinia C, Vitolinia V, Vitalind C Bl 2; Swed. Ascoval†, Macalvit, Switz. Alca-C, Ascosal; Aspirine C; C-Calcium; Ca-C†; Calcium D Sauter; Callimon†; Cemaquin; Conte-Douleurs C; Dafalgan plus C; Demogripal C; Desaquick Varta fresh†; Desaquick forte†; Desaquick fresh†; DoloCitran C; Esberitop; Escogripp sans codeine; Gramipan†; Grippostad C†; Influbene C; Instacyl; Neo Citran sans codeine; Gramipan†; Grippostad C†; Influbene C; Instacyl; Neo Citran Grippe/erfordissement. Neo-Angin avec vitamin C sans sucre; Neo-Codion N; No Grip C†; Panadol C; Phakolen†; Pretuval C; Redoxon + Zinc; Rhinofebral†; Treupel Grippe; Treupel simplex†; Visaline; Zolben C; Thali. Biocalron; Blackmores Naturetime Buffered C; Ca-C; Cyclo 3 Fort; Detoch†; Nat-C Medicrafts; Rhinophen-C†; Sentril; Strepsils Plus Vit C; Turk: Afebryl; Aspinin plus C; Calcium-Sandoz C; Epargriseovit; Mentimol; Sedergine Vit-C; Strepsils C; Vicks Pastl; Zinco C; UK; Beechams Cold & Flu; Beechams Flu-Plus; Beechams for Natural Defence; Boots Cold & Flu; Beechams Flu-Plus; Beechams for Natural Defence; Boots Cold & Flu; Beechams Flu-Plus; Beechams for Natural Defence; Boots Cold & Flu; Beechams Flu-Plus; Beechams for Natural Defence; Boots Cold & Flu; Beechams Flu-Plus; Beechams for Natural Defence; Boots Cold & Flu; Beechams Flu-Plus; Beechams for Natural Defence; Boots Cold & Flu; Beechams Flu-Plus; Beechams for Natural Defence; Boots Cold & Flu; Beechams flu-Plus; Beechams flu-Plu Relief; Boots Cold & Flu Relief Hot Lemon; Cold Relief; Goodypops; Hacks; Hacks Blackcurrant; Hematinic; Lemsip Cold & Flu Breathe Easy; Lemsip Cold & Flu Max Strength; Lemsip Cold & Flu Original; Lemsip Non-Decongestant; Moviprep; Olbas Powerflu plus Vitamin C; Paracets Cold Relief; Redoxon Double Action; Resolve; Strepsils with Vitamin C; Strepsils Zinc Defence†; Top C; Uniflu with Gregovite C; Vicks Vital†; **USA:** Amino-Opti-C; C Factors "1000" Plus; Citrus-flav C; Ester-C Plus; Ester-C Plus Multi-Mineral; Hemocyte Plus; Pan C; Peridin-C; Proflavanol; Span C; Sucrets Defense Kids Formula; **Venez.:** Calcebion; Cepin; Dremo-K†; Kalsis; Multidex; Ro-C-Var: Terace Zinc

Used as an adjunct in: Arg.: Anemidox-Ferrum; Anemidox-Solutab; Ferro Folic; Ferrocebrina; Hierro Folico; Hierro Plus; Iberol; Rubiron; Sideralce; Austral.: Bio Iron; Ferrograd C; Austria: Ferretab; Ferrograd C; Liquifer†; Losferron; Losferron-Fol; Belg.: Fero-Grad; Losferron; Braz.: Anemofer†; Cobaldoze; Combiron; Dobiron; Ferrocomplex; Ferroplex; Ferrotonico B12†; Iberin Folico; Iberol; Iloban; Novofer; Rubralong†; Rubrargil; Sulfato Ferroso Composto; **Canad.:** Fero-Grad; Iberet†; Neo-Fer CF; Palafer CF; Chile: Confer; Cronofernit; Ferranen; Ferranin; Ferro F-500 Gradumett; Ferro Vitaminico; Folifer; Iberol; Iberol Folico; Cz.: Ferro-Folgamma; Losfernor, Sorbifer; Tardyferon; Tardyferon-Fol; Fin.: Duroferon; Fr.: Fero-Grad vitamine C; Tardyferon; Tardyferon B; Timoferol; Ger.: Ferro-Folgamma; Kendural C; Kendural-Fol-500; Losferron; Tardyferon; Tardyferon-Fol; **Hong** Kong: Iberet; Iberet-Folic; Hung:: Ferro-Folgamma; Sorbifer; Tardyferon-Fol; India: Anemidox; Autrin; Conviron-TR; Raricap; Siderfol; Softeron; Indon: Adfer; Biosanbe; Dasabion; Emibion; Emineton; Fercee; Feritrin; Ferofort; Habebion; Hemarate CE; Hemobion; Iberet; Iberet-Folic; Inbion; Natabion; Neogobion; Nichobion; Odiron-C; Opibion; Prenamia; Sangobion; Sangofer; Sangovitin; Tropifer; Viliron; Vitabion; Vitalex; Vitonal-F; Irl.: Fer-Sangovier, Sangovier, Tripier, Villroli, Vitalex, Vitoria-F, Mr. Per-rograd C, Fdu. Auxofer, Bioferal, Biogludier, Blizer, Blustark; Crom; Crom-atonferro; Effegyn; Emonorm†; Eriglobin; Eritropiu; Ferig Ferro Complex; Ferrograd C; Ferrograf Folic; Ferrogyn; Rexifer†; Gloros; Liquifer†; Losfer-ron; Megafer; Monoferro; Prontoferro; Sidervim; Malaysia: Iberet-Folic; Iberet†; Odiron-C†; Sangobion; Mex.: Autrin†; Ferro Folico; Fumarol; Iberet; Iberol; **Neth.:** Losferron; **Norw.:** Duroferon; **NZ:** Ferrograd C; **Philipp.:** Iberet; Iberet-Folic; Imefer; Macrobee with Iron; Magniferron; Micron-C; Molvite with Iron; Mulvitron; Odiron-C; Sangobion; Sorbifer; Terracron-c; Plovite With Iron; Pluiviron; Odiron-c; Sangopion; Sorbier; Tardyferon; Tar-ferron; Tri-HMIC; Pol.: Additiva Ferrum; Ascofer; Sorbier; Tardyferon; Tar-dyferon-Fol; Rus.: Fenules (Фенольс); Ferro-Folgamma (Ферро-Фольгамма); Ferroplex (Ферроплекс); Gyno-Tardyferon (Гино-тардиферон); Sorbier (Сорбифер); Ayfr: Autrin; Fero-Folic; Fero-Grad; Foliglobin; Singapore: Iberet; Iberet-Folic; Iron Melts; Neogobion; Odiron-Folgiobin; Singapore: Iberet; Iberet-Folic; Iron Metts; Neogobion; Odirion-C, Sangobion; Switzz. Diofer: Duofer Fol; Fero-Folic; Ferrascothin; Kend-ural; Loesfer†; Lufer; Thai.: Glufer-C; Iberet†; Trinsicon†; Turk.: Ferro-Vital; Gyno-Tardyferon; Vi-Fer; UK: Ferrograd C; USA: Anemagen†; Cevi-Fer† Chromagen; Chromagen FA; Chromagen Forte; Contrin; Feocyte; FeoGen; Fero-Folic; Fero-Grad; Ferotrinsic; Ferralet Plus†; Ferrex Forte Plus†; Ferrex Plus; Ferrogels Forte; Fetrin; Fumatinic; Hem Fe; Hemaspan; Hematinic Plus; I-L-X; Iberet-Folic; Iberet; Icar-C Plus; Irospan; Livitrinsic-f; Niferex, Niferex Forte; Pronema Hematinic; Olfrinic; Tirl-HMC; Trinsicon; Vitron-C; **Venez.**: Autrin; Fefo!; Ferror-Folic; Ferro-Folic; Ferroce; Ferroce con B12; Ferronorm; Hepafol con B-12; Iberol C.

## Vitamin D Substances

Vitamina D.

The term vitamin D is used for a range of closely related sterol compounds including alfacalcidol, calcifediol, calcitriol, colecalciferol, dihydrotachysterol, and ergocalciferol. Newer vitamin D analogues include doxercalciferol, falecalcitriol, maxacalcitol, and paricalcitol.

### Alfacalcidol (BAN, rINN)

Alfacalcidolum; Alfakalcidol; Alfakalcidolis; Alfakalsidol; Alfakalsidoli; EB-644; I  $\alpha$ -Hydroxycholecalciferol; I  $\alpha$ -Hydroxyvitamin  $D_3$ ;  $I\alpha$ -OHD<sub>3</sub>. (5Z,7E)-9,10-Secocholesta-5,7,10(19)-triene- $I\alpha$ ,3βdiol.

Альфакальцидол

 $C_{27}H_{44}O_2 = 400.6.$ CAS — 41294-56-8. ATC — AIICCO3. ATC Vet - QAIICC03.

Pharmacopoeias. In Chin. and Eur. (see p.vii).

Ph. Eur. 6.2 (Alfacalcidol). White or almost white crystals which are sensitive to air, heat, and light. Practically insoluble in water; freely soluble in alcohol; soluble in fatty oils. Reversible isomerisation to pre-alfacalcidol takes place in solution, depending on temperature and time. Activity is due to both compounds. Store at 2° to 8° under an atmosphere of nitrogen in airtight containers. The contents of an opened container should be used immediately. Protect from light.

### Calcifediol (BAN, USAN, rINN)

Calcidiol; Calcifediolum; Calcifediolum Monohydricum; 25-Hydroxycholecalciferol; 25-Hydroxyvitamin D<sub>3</sub>; Kalcifediol; Kalcifediol monohydrát; Kalcifediolis; Kalcyfediol; Kalsifedioli; 25-(OH)D $_3$ ; U-32070E. (5Z,7E)-9,10-Secocholesta-5,7,10(19)-triene-3 $\beta$ ,25-diol monohydrate.

Кальцифедиол

 $C_{27}H_{44}O_2, H_2O = 418.7.$ 

CAS — 19356-17-3 (anhydrous calcifediol); 63283-36-3 (calcifediol monohydrate).

ATC - AIICCO6.

ATC Vet - QAIICCO6.

Pharmacopoeias. In Eur. (see p.vii) and US.

Ph. Eur. 6.2 (Calcifediol). White or almost white crystals which are sensitive to air, heat, and light. Practically insoluble in water; freely soluble in alcohol; soluble in fatty oils. Reversible isomerisation to pre-calcifediol takes place in solution, depending on temperature and time. The activity is due to both compounds. Store at 2° to 8° under an atmosphere of nitrogen in airtight containers. The contents of an opened container should be used immediately. Protect from light.

USP 31 (Calcifediol). Store in airtight containers. Protect from light.

#### Calcitriol (BAN, USAN, rINN)

Calcitriolum; 1,25-Dihydroxycholecalciferol; 1\alpha,25-Dihydroxycholecalciferol;  $1\alpha$ ,25-Oihydroxyvitamin D<sub>3</sub>; Kalcitriol; Kalcitriolis; Kalsitriol; Kalsitrioli,  $1\alpha$ ,25(OH)<sub>2</sub>D<sub>3</sub>; Ro-21-5535. (5Z,7E)-9,10-Secocholesta-5,7,10(19)-triene- $1\alpha$ ,3 $\beta$ ,25-triol.

Кальцитриол

 $C_{27}H_{44}O_3 = 416.6.$ 

CAS — 32222-06-3 (anhydrous); 77326-95-5 (monohy-

ATC - AIICCO4; D05AX03

ATC Vet - QAIICC04; QD05AX03.

Pharmacopoeias. In Eur. (see p.vii) and US.

Ph. Eur. 6.2 (Calcitriol). White or almost white crystals. Practically insoluble in water; freely soluble in alcohol; soluble in fatty oils. It is sensitive to air, heat, and light. A reversible isomerisation to pre-calcitriol takes place in solution, depending on temperature and time. The activity is due to both compounds. Store at 2° to 8° under an atmosphere of nitrogen in airtight containers. The contents of an opened container should be used immediately. Protect from light.

USP 31 (Calcitriol ). It may be anhydrous or contain one molecule of hydration. White or almost white crystals. Practically insoluble in water: freely soluble in alcohol; soluble in ether and in fatty oils. Store in airtight containers. Protect from light.

#### Colecalciferol (BAN, rINN)

Activated 7-Dehydrocholesterol; Cholécalciférol; Cholecalciferol; Cholecalciferolum; Cholekalciferol; Cholekalciferolis; Choleka-Icyferol: Colécalciférol: Colecalciferolum: Kolekalciferol: Kolekalsiferol; Kolekalsiferoli; Vitamin D<sub>3</sub>. (5Z,7E)-9,10-Secocholesta-5,7,10(19)-trien-3β-ol.

Колекальциферол

 $C_{27}H_{44}O = 384.6.$ 

CAS — 67-97-0.

ATC — AIICC05. ATC Vet - QAIICC05.

Description. Colecalciferol is the naturally occurring form of vitamin D. It is produced from 7-dehydrocholesterol, a sterol present in mammalian skin, by ultraviolet irradiation.

Pharmacopoeias. In Chin., Eur. (see p.vii), Int., Jpn, US, and Viet.

Eur. also includes monographs for concentrates in an oily form, a powder form, and a water-dispersible form. US also includes a solution

Ph. Eur. 6.2 (Cholecalciferol; Colecalciferol BP 2008). White or almost white crystals which are sensitive to air, heat, and light, Practically insoluble in water; freely soluble in alcohol; soluble in trimethylpentane and in fatty oils. Solutions in solvents without an antoxidant are unstable and should be used immediately. A reversible isomerisation to pre-colecalciferol takes place in solution, depending on temperature and time. The activity is due to both compounds. Store under nitrogen in airtight containers at a temperature of 2° to 8°. The contents of an opened container should be used immediately. Protect from light.

The BP 2008 directs that when calciferol or vitamin D is prescribed or demanded, Colecalciferol or Ergocalciferol shall be dispensed or supplied.

Ph. Eur. 6.2 (Cholecalciferol Concentrate (Oily Form); Cholecalciferolum Densatum Oleosum; Colecalciferol Concentrate (Oily Form) BP 2008). A solution of colecalciferol in a suitable vegetable oil. It contains not less than 500 000 units/g. It may contain suitable stabilisers such as antoxidants. A clear, yellow liquid. Practically insoluble in water; slightly soluble in dehydrated alcohol; miscible with solvents of fats. Partial solidification may occur, depending on the temperature. Store in well-filled airtight containers. Protect from light. The contents of an opened container are to be used as soon as possible; any unused part is to be protected by an atmosphere of nitrogen.

Ph. Eur. 6.2 (Cholecalciferol Concentrate (Powder Form); Cholecalciferoli Pulvis; Colecalciferol Concentrate (Powder Form) BP 2008). It is obtained by dispersing an oily solution of colecalciferol in an appropriate matrix which is usually based on a combination of gelatin and carbohydrates of suitable quality. It contains not less than 100 000 units/g. It may contain suitable stabilisers such as antoxidants. White or yellowish-white, small particles. Depending on their formulation, it may be practically insoluble in water or may swell or form a dispersion. Store in well-filled airtight containers. Protect from light. The contents of an opened container are to be used as soon as possible; any unused part is to be protected by an atmosphere of nitrogen.

Ph. Eur. 6.2 (Cholecalciferol Concentrate (Water-dispersible Form); Cholecalciferolum in Aqua Dispergibile; Colecalciferol Concentrate (Water-dispersible Form) BP 2008). A solution of colecalciferol in a suitable vegetable oil to which suitable solubilisers have been added. It contains not less than 100 000 units/g. It may contain suitable stabilisers such as antoxidants. A slightly yellowish liquid of variable opalescence and viscosity. Highly concentrated solutions may become cloudy at low temperatures or form a gel at room temperature. Store in well-filled airtight containers. Protect from light. The contents of an opened container are to be used as soon as possible; any unused part is to be protected by an atmosphere of inert gas.

USP 31 (Cholecalciferol). White, odourless crystals. Insoluble in water; soluble in alcohol, in chloroform, and in fatty oils. M.p. about 85°. It is affected by air and light. Store under nitrogen in hermetically sealed containers at a temperature of 8° to 15°. Protect from light.

USP 31 (Cholecalciferol Solution). A solution of colecalciferol in an edible vegetable oil, in polysorbate 80, or in propylene glycol. Store in airtight containers. Protect from light.

# Dihydrotachysterol (BAN, rINN)

Dichysterol; Dihidrotakisterol; Dihidrotaquisterol; Dihydrotachystérol; Dihydrotachysterolum; Dihydrotakisterol; Dihydrotakysterol; Dihydrotakysteroli. (5E,7E,22E)-10α-9,10-Secoergosta-5.7.22-trien-3B-ol.

Дигидротахистерол

 $C_{28}H_{46}O = 398.7$ 

CAS — 67-96-9.

ATC - AIICC02

ATC Vet — QAIICC02.

Pharmacopoeias. In Eur. (see p.vii) and US.

Ph. Eur. 6.2 (Dihydrotachysterol). Colourless crystals, or a white or almost white crystalline powder. It exhibits polymorphism. Practically insoluble in water; sparingly soluble in alcohol; freely soluble in acetone and in n-hexane. Store under an inert gas in airtight containers at 2° to 8°.

USP 31 (Dihydrotachysterol). Colourless or white, odourless crystals, or white, odourless, crystalline powder. Practically insoluble in water: soluble in alcohol: freely soluble in chloroform and in ether; sparingly soluble in vegetable oils. Store in hermetic glass containers from which the air has been displaced by an inert gas. Protect from light.