

## Vitamin D Substances

Vitamina D.

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

### Alfalcidol (BAN, rINN)

Alfalcidolum; Alfalcidol; Alfalcidolis; Alfakalsidol; Alfakalsidoli; EB-644; 1 $\alpha$ -Hydroxycholecalciferol; 1 $\alpha$ -Hydroxyvitamin D<sub>3</sub>; 1 $\alpha$ -OH-D<sub>3</sub>. (5Z,7E)-9,10-Secosterolesta-5,7,10(19)-triene-1 $\alpha$ ,3 $\beta$ -diol.

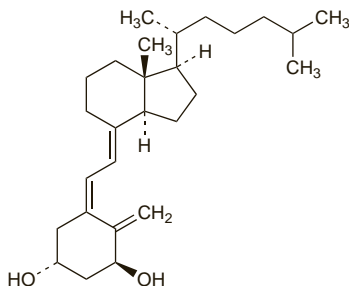
Альфакальцидол

C<sub>27</sub>H<sub>44</sub>O<sub>2</sub> = 400.6.

CAS — 41294-56-8.

ATC — A11CC03.

ATC Vet — QA11CC03.



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

**Ph. Eur. 6.2** (Alfalcidol). 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-alfalcidol 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; Calcifédiol; Calcifediolum; Calcifediolum Monohydratum; 25-Hydroxycholecalciferol; 25-Hydroxyvitamin D<sub>3</sub>; Kalcifediol; Calcifedioli monohydrát; Kalcifediolis; Kalcifedioli; Kalsifedioli; 25-(OH)D<sub>3</sub>; U-32070E. (5Z,7E)-9,10-Secosterolesta-5,7,10(19)-triene-3 $\beta$ ,25-diol monohydrate.

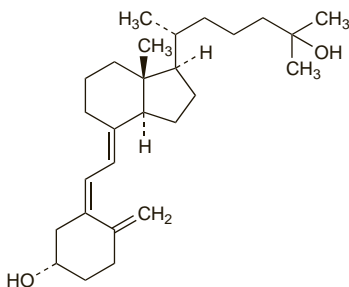
Кальцифедиол

C<sub>27</sub>H<sub>44</sub>O<sub>2</sub>·H<sub>2</sub>O = 418.7.

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

ATC — A11CC06.

ATC Vet — QA11CC06.



**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-Dihydroxyvitamin 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-Secosterolesta-5,7,10(19)-triene-1 $\alpha$ ,3 $\beta$ ,25-triol.

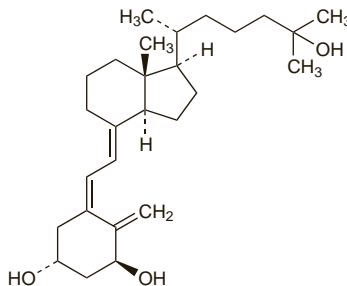
Кальцитриол

C<sub>27</sub>H<sub>44</sub>O<sub>3</sub> = 416.6.

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

ATC — A11CC04; D05AX03.

ATC Vet — QA11CC04; 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; Colecalciferol; Colecalciferolum; Cholecalciferolum; Cholecalciferol; Cholecalciferolis; Cholecalciferol; Colecalciferoli; Colecalciferolum; Kolecalciferol; Kolecalciferoli; Vitamin D<sub>3</sub>. (5Z,7E)-9,10-Secosterolesta-5,7,10(19)-trien-3 $\beta$ -ol.

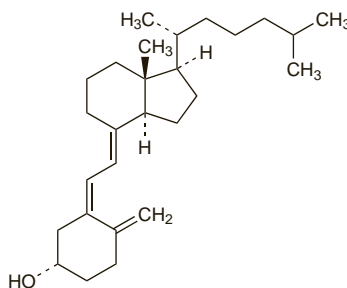
Колекальциферол

C<sub>27</sub>H<sub>44</sub>O = 384.6.

CAS — 67-97-0.

ATC — A11CC05.

ATC Vet — QA11CC05.



**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 antioxidant 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 antioxidants. 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 antioxidants. 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 Dispersibile; Colecalciferol Concentrate (Water-dispersible Form) BP 2008). A solution of colecalciferol in a suitable vegetable oil to which suitable stabilisers have been added. It contains not less than 100 000 units/g. It may contain suitable stabilisers such as antioxidants. 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; Dihidrotakisterol; Dihydrotachysterol; Dihydrotachysterolum; Dihidrotakisterol; Dihydrotakysterol; Dihydrotakysteroli. (5E,7E,22E)-10 $\alpha$ -9,10-Secosterolesta-5,7,22-trien-3 $\beta$ -ol.

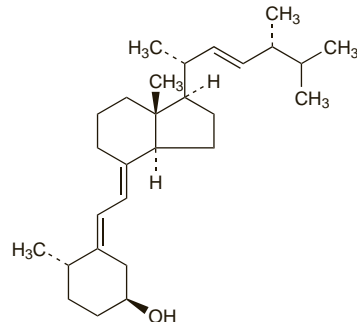
Дигидротакистерол

C<sub>28</sub>H<sub>46</sub>O = 398.7.

CAS — 67-96-9.

ATC — A11CC02.

ATC Vet — QA11CC02.



**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.