CALCIFEDIOL Ph. Eur./USP/IP/BP

(25-Hydroxycholecalciferol)

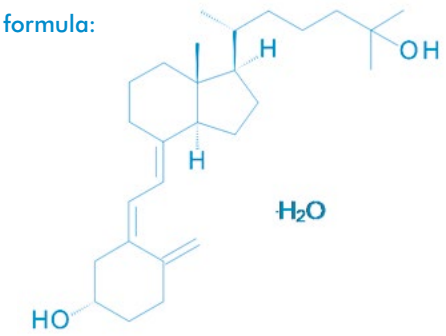
CARBOGEN AMCIS
A Dishman Group Company

Calcifediol is a vitamin D3 analog for the Pharmaceutical and Veterinary industry. Calcifediol is especially used to prevent and treat osteoporosis or decalcification of bones. The substance is also active against other bone growth disorders such as rickets, osteomalacia and specific liver and parathyroid glands abnormalities. It is also used for the treatment and prevention of secondary hyperparathyroidism associated with chronic kidney disease (CKD).

CARBOGEN AMCIS manufactures this API under cGMP regime at its HIPO manufacturing facility in Veenendaal, the Netherlands.

Specification: Chemical name: Calcifediol; 25-hydroxyvitamin D3; 25-hydroxycholecalciferol; 25-HCC
Content Calcifediol (HPLC) is 97.0-102.0%
CAS 63283-36-3 (monohydrate), 19356-17-3 (anhydrous)

•• **Structural formula:**



CAS no. 63283-36-3 (monohydrate), 19356-17-3 (anhydrous)

Toxic classification: Harmful (category Xn). Before handling this substance, read the special directions on the label and Safety Data Sheet (available upon request).

Regulatory: CEP/CoS and DMF available.

Application: Pharmaceutical and Veterinary industry. Suitable for drug formulation including tablets, oral solutions and soft gel capsules.

ARS - Working Standard

Calcifediol – CAS no. 63283-36-3

Available Impurities

Impurity A (25-hydroxylumisterol) - CAS no. 61585-29-3

Impurity B (25-hydroxy-7-dehydrocholesterol) - CAS no. 22145-68-2

Impurity C (25-hydroxytachysterol) – CAS no. 39932-44-0

Impurity D (trans-25-hydroxyvitamin D3) – CAS no. 1233749-00-2

BRINGING YOUR SCIENCE TO LIFE

The information given in this product information bulletin is based on our current knowledge and experience. It does not relieve users or processors from carrying out their own precautions and tests. Any relevant rights and existing legislation and regulations must be observed.



CARBOGEN AMCIS B.V.
Nieuweweg 2a, 3901 BE Veenendaal
The Netherlands
Tel: +31 318 545 754
Cholesterol & Vitamin D - Asia, Oceania | Cholesterol SF Worldwide: edo.pieters@carbogen-amcis.com
Cholesterol & Vitamin D - Europe: chantal.hoevenaars@carbogen-amcis.com
Cholesterol & Vitamin D - Americas, Southern Europe, Africa, Middle East: gabriel.moreira@carbogen-amcis.com
www.carbogen-amcis.com

CARBOGEN AMCIS is a leading service provider, offering a portfolio of drug-development and commercialization services to the pharmaceutical and biopharmaceutical industry at all stages of drug development. The integrated services provide innovative chemistry solutions to support timely and safe drug development allowing customers to make the best use of available resources. CARBOGEN AMCIS is also active in the marketing/sales and manufacture of Vitamin D analogues, Vitamin D, Cholesterol and lanolin related products for key markets as pharmaceutical, cosmetic, food, feed as well as industry applications.

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