

## Vi-De 3®

Pure crystalline vitamin D<sub>3</sub> (cholecalciferol)

### COMPOSITION

#### Oral solution

1 ml (= 45 drops) contains cholecalciferol 4500 IU, ethanol 65.36%/vol, excipients

#### Injection solution

1 ml (= 1 ampoule) contains cholecalciferol 300 000 IU, excipients: sodium citrate, butyl alcohol, isobutyl alcohol, propyleneglycol, PEG-40 castor oil 80 mg, water

### PROPERTIES/ACTIONS

Vitamin D, which is effective in therapeutic use when given either orally or parenterally, is a naturally occurring hormone in humans, being formed from 7-dehydrocholesterol in the skin as a result of exposure to sunlight (ultraviolet irradiation). It is also obtained in small quantities from dietary sources such as milk, butter, liver and egg yolks. Vitamin D regulates calcium and phosphate metabolism, its main function being to mediate intestinal calcium absorption by an active transport mechanism. It also promotes normal bone formation. The minimum daily requirement of vitamin D is 100–400 IU, depending on age.

### PHARMACOKINETICS

Vitamin D<sub>3</sub> is rapidly absorbed from the proximal and distal small intestine and transported to its main storage sites (liver and adipose tissue) bound to specific  $\alpha$ -globulins.

Following i.v. injection elimination of both unchanged substance and metabolites is biphasic. Vitamin D<sub>3</sub> is biotransformed in the liver to 25-hydroxycholecalciferol (25-HCC; calcifediol), which then undergoes further hydroxylation at position 1 in the kidneys to give the active metabolite 1,25-dihydroxycholecalciferol (1,25-DHCC; calcitriol). Vitamin D is stored in the body and is excreted mainly in the form of inactive glucuronides. It is excreted both in faeces via the bile and in urine.

### INDICATIONS/USES

- Prevention of rickets
- Treatment of all forms and stages of rickets
- Osteomalacia
- Hypocalcaemic tetany
- Acute postoperative hypoparathyroidism
- Chronic hypoparathyroidism

### DOSAGE/ADMINISTRATION

#### Prevention of rickets

Full-term infants: 400 IU (= 4 drops) daily in the first year of life, starting in week 2–5

Preterm infants: 400–800 IU (= 4–8 drops) daily in the first year of life

#### Treatment of rickets

Dosage should be individualized on the basis of frequent determinations of serum calcium and bone X-rays.

#### Florid rickets

5000 IU (= 50 drops) daily for 3 weeks

#### Acute postoperative hypoparathyroidism; tetany

Start by giving 300 000 IU i.m. in combination with i.v. calcium and repeat as necessary depending on the patient's calcium blood level.

### Instructions for use of the oral solution

Add the required number of drops to food or a drink.

### RESTRICTIONS ON USE

#### Contraindications

To use of Vi-De 3 for rickets prevention in infants: hypothyroidism, idiopathic hypercalcaemia, vitamin-D hypersensitivity. To high-dose vitamin-D therapy in adults: skeletal disorders involving complete immobilization (which increases calcium excretion), sarcoidosis (Boeck's disease), acute pulmonary tuberculosis, immobilization following corrective orthopaedic surgery. Vi-De 3 should not be given by intravenous injection. Concomitant administration of vitamin-D analogues.

#### Precautions

Caution is required in patients with disturbances of calcium metabolism, kidney failure, kidney stones, arteriosclerosis or coronary disease. All forms of vitamin D are toxic in high doses, causing a significant increase in calcium absorption. Toxic effects may also occur if doses of 1000–3000 IU/kg bodyweight daily are administered over a period of several months. The fact that milk, fats and baby or other foods are often enriched with vitamin D should be taken into account when determining dosage. Caution should be exercised in patients receiving treatment with cardiac glycosides since hypercalcaemia may lead to arrhythmia in such cases.

Particular care should be taken to avoid the following:

- Prophylactic administration of vitamin D in large doses over a period of months or

even years without proper monitoring or a specific indication, especially in conjunction with calcium and/or vitamin-enriched foods (e.g. babyfoods).

- Massive doses of vitamin D at short intervals.

This is because the body's attempts to eliminate the resultant calcium excess might overload the excretory capacity of the kidneys; the first symptoms of overdosage are polyuria and polydipsia.

Patients receiving the recommended dose of Vi-De 3 for the prevention of rickets or osteomalacia or as a supplement to the normal diet should avoid other drugs containing vitamin D and vitamin-D enriched foods. Particular care should be exercised in the prophylactic use of vitamin-D preparations in infants receiving vitamin-D enriched babyfoods (normally containing 400 IU per daily portion).

The recommended dose should be taken regularly but not exceeded. Care should be taken that patients receive sufficient dietary calcium. Regular blood calcium checks should be performed on patients receiving long-term treatment for vitamin-D-resistant rickets.

#### Pregnancy and lactation

Vi-De 3 may be taken by women who are pregnant or breastfeeding at a dosage corresponding to the normal daily requirement. There is clear evidence that doses in excess of the daily requirement represent a risk to the foetus, although this may be outweighed by the therapeutic benefit to the mother.

### ADVERSE REACTIONS

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