41594_PIL_P2

BIOGEN
FOR THE RESULTS YOU WANT

VITAMIN D_3

PROFESSIONAL INFORMATION

Complementary Medicine: Health Supplement
D 34.11 Vitamins

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.
Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE
BIOGEN VITAMIN D_3

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

EACH 1 ml SPRAY CONTAINS:

Vitamin D_3 (Cholecalciferol)	1 000 IU / 25 µg

For a full list of excipients, see section 6.1.
Contains sweetener (0,04 g steviol glycosides per spray).

3. PHARMACEUTICAL FORM
Liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Vitamin D contributes to the development and maintenance of strong bones and teeth. It contributes to the maintenance of normal muscle function, and contributes to the normal function of the immune system. It also assists in the absorption and use of calcium and phosphorus, to normal cell division, and is a factor in the maintenance of good health.

4.2 Posology and method of administration
Adults and children: Take one spray daily. Shake well before use. For optimal absorption, spray into your mouth, ideally onto the soft tissue of the mouth, hold for 30-90 seconds before swallowing.

4.3 Contraindications:
- Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.
- Patients with hypercalcaemia or renal osteodystrophy with hyperphosphatemia.

4.4 Special warnings and precautions for use
- Vitamin D may increase calcium levels and increase the risk of arteriosclerosis in renal failure.
- Patients with calculi or heart disease should have plasma phosphate concentration carefully controlled and monitored to reduce the risk of ectopic calcification.
- Vitamin D may increase calcium levels in patients with histoplasmosis, hyperparathyroidism, sarcoidosis, and tuberculosis. The metabolism to calcitriol is increased, which may cause hypercalcemia and complications such as kidney stones and calcified tissue.

4.5 Interaction with other medicines and other forms of interaction
- Some anticonvulsants (phenytoin, barbiturates, primidone) may reduce the effect of Vitamin D by accelerating its metabolism.
- The effect of calcitonin may be antagonised by Vitamin D.
- High doses of Vitamin D can cause hypercalcaemia. Hypercalcaemia increases the risk of fatal cardiac arrhythmias with digoxin.
- Thiazide diuretics decrease urinary calcium excretion, which could lead to hypercalcaemia if Vitamin D supplements are taken concurrently.
- Patients may be at increased risk of hypercalcaemia if Vitamin D is given with calcium or phosphate, as Vitamin D increases the active absorption of calcium and phosphorous.

4.6 Fertility, pregnancy and lactation
Vitamin D is likely safe when used within the recommended dosage. There is a risk of hypercalcaemic tetany in breast-fed infants whose mothers take excessive doses of Vitamin D during pregnancy.

4.7 Effects on ability to drive and use machines
No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that BIOGEN VITAMIN D_3 does not adversely affect their performance.

4.8 Undesirable effects
Uncommon: Vitamin D toxicity when taken in excessive doses- symptoms include: hypercalcaemia, azotemia, and anaemia.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: *https://www.sahpra.org.za/Publications/Index/8.*

4.9 Overdose
Overdose may lead to the development of hypercalcaemia or hyperphosphatemia, of which symptoms may include: anorexia, lassitude, nausea and vomiting, constipation or diarrhea, polyuria, nocturia, sweating, headache, thirst, somnolence, and vertigo.
Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
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D 34.11 Vitamins

Vitamin D
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5.2 Pharmacokinetic properties
Vitamin D
Vitamin D is well absorbed from the gastrointestinal tract with the aid of bile. Absorption may be decreased in patients with decreased fat absorption. Vitamin D and its metabolites circulate in the blood bound to a specific α-globulin. It is converted by hydroxylation, predominantly in the liver, to calcitriol, which is the main biologically active form of Vitamin D. Small amounts are stored in the liver, as well as in adipose tissue. The metabolites of Vitamin D analogues are excreted mainly in bile and faeces, with only small amounts appearing in urine. Although some Vitamin D that is excreted in bile is reabsorbed in the small intestine, enterohepatic circulation does not appear to be an important mechanism for the conservation of the Vitamin. Certain Vitamin D substances may be distributed into breast milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
MCT oil, flavour, and steviol glycosides.

6.2 Incompatibilities
Not applicable

6.3 Shelf Life
24 Months

6.4 Special precautions for storage
Store all medicines out of reach of children.
Store at or below 25 °C and protect from moisture.
Store in the original container.

6.5 Nature and contents of container
30 ml Liquid in a amber glass container with a spray cap.

6.6 Special precautions for disposal
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Biogen
23 Stag Road,
Glen Austin,
South Africa
info@biogen.co.za
www.biogen.co.za
Tel: 011 589 2322

8. REGISTRATION NUMBER
Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION
Will be allocated by SAHPRA upon registration.

2726P01

JOB: BPS_VitaminD3 Oral Spray 30ml	**SIZE:** 210mm x 180mm
STOCK: Foil Substrate: ☐ Clear Substrate: ☐ White Substrate: ☐ Paper: ☒ Other: ☐	
COLOUR: ■ K	**FINISHING:** ☐ Foil / Holographic Foil ☐ Matte ☐ Gloss ☐ Spot UV ☐ Doming ☐ Embossing
PLEASE CHECK CAREFULLY Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.	