

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

D-Drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0,5 ml contains
500 IU Vitamin D3 (Cholecalciferol) and
3,63 IU Vitamin E

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Golden yellow odourless oily liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

D-DROPS is a Vitamin D supplement used to supplement a diet lacking in vitamin D.

4.2 Posology and method of administration

Adults and children 1 year and older:

Take 1ml once daily or 0,5 ml twice daily, or as directed by a healthcare professional.

Shake the bottle before use.

4.3 Contraindications

None.

4.4 Special warnings and precautions for use

Use in children under the age of 1 year is at the discretion of a healthcare professional.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies were performed on D-Drops. The following interactions are noted on the monograph of the active ingredient:

- High doses of Vitamin D may cause hypercalcaemia in patients taking the following medicines concurrently: digoxin, diltiazem, thiazide diuretics, verapamil.
- Vitamin D may induce the enzyme cytochrome P450 (CYP3A4) resulting in reduced bioavailability of other medicines metabolized by this enzyme, for example atorvastatin.

4.6 Fertility, pregnancy and lactation

Vitamin D supplementation is suitable for use during pregnancy and lactation at the recommended dose and under the supervision of a healthcare professional.

4.7 Effects on ability to drive and use machines

The effects on ability to drive and use machines has not been studied.

4.8 Undesirable effects

Vitamin D is well tolerated when taken in appropriate doses.

4.9 Overdose

When Vitamin D is taken in excessive doses, intoxication can occur. Symptoms of vitamin D toxicity include hypercalcaemia, azotemia,

anaemia, osteoporosis in adults, decreased growth in children, weight loss, dry mouth, hypertension and seizures.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Health Supplement
D34.11 Vitamins

5.2 PHARMACOLOGICAL ACTION

- Vitamin D is an essential fat-soluble vitamin which contributes to normal immune function, maintenance of normal muscle function, cell division, and the development and maintenance of strong bones and teeth.
- Vitamin D helps in the absorption and use of calcium and phosphorus and contributes to normal calcium levels in the body.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sunflower oil.
Sugar free.

6.2 Incompatibilities

Unknown

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C. Keep bottle tightly closed and protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

D-Drops are packed in amber dropper bottles with 30ml.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER

To be allocated.

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority for its quality, safety or intended use.

9 DATE OF PUBLICATION OF PROFESSIONAL INFORMATION

September 2020