



## PRODUCT SPECIFICATION SHEET

### Vitamin D3 200-500 IU/drop

Version no: 1.3.0

Author: A Fleet

Revised by: AK,  
ARF, RKK

Date: 21.03.2021

#### General description:

Vitamin D3 drops containing 200-500 IU of vitamin D3 per drop, in a 10- 30ml bottle with a dropper. drops/ bottle pack.

#### Technical specifications:

Vitamin D3 drops containing 200-500 IU of vitamin D3 per drop, in a 15 or 30ml bottle with a dropper. Drops/ Bottle pack.

#### Technical specifications:

Oral solution containing vitamin D equivalent to 200-500IU/drop, preferably 400IU/drop of cholecalciferol in a bottle of 10- 30 ml with a calibrated dropper. Dropper, preferably, 1 drop equivalent to 400 IU.

Oral liquid is packed with a dropper bottle.

#### Acceptable pharmacopoeia

Should comply with at least one of the pharmacopeias:

British Pharmacopoeia (BP)

United States Pharmacopoeia (USP)

European Pharmacopoeia (Ph.Eur)

International Pharmacopoeia (Ph.Int)

#### Indications:

Prevention of vitamin D deficiency

#### Dosage, instruction for use

Recommended Dosage

Infants older than 1 month and children below the age of 12 years: only 1 drop (not more than, 400 IU/10 mcg) daily, or as directed by physician.

Children older than 12 years, pregnant women and other adults: 1-2 drops (Equivalent to/not more than, 400 IU/10 mcg per drop, given daily, or as directed by physician.

<https://www.healthynewbornnetwork.org/hnn-content/uploads/NewBornHealthBook-Production2017-V4b-WEB.pdf>

**Shelf life:** Minimum 24 months, preferably 36 months.

**Stability study data-** Preferred Zone IVb

#### Storage and transportation:

Do not store above 30°C. Protect from light and moisture. Keep out of the reach and sight of children.

**Packaging and labelling:**

A Patient Information Leaflet should be attached or enclosed in a box with each bottle.

Each dose is to be administered by means of a device suitable for measuring the prescribed volume (usually graduated by the measurement at 1 drop equivalent to / not more than 400 IU of cholecalciferol. The measuring device should be enclosed with or attached to each bottle and will require validation reports for the same)

**Primary packaging:**

Primary packaging should be sterile and protect the product from light, heat and microbiological contamination.

Primary label Labels must have adequate information to permit identification, safe transport, storage and use of the product throughout its shelf life. The writing on primary and secondary packs must be in indelible ink.

The label shall contain the following information:

- Name and address of the manufacturer and packer, or distributor, or importer, or exporter, or vendor and country of origin
- Net weight
- Batch number clearly identified and visible
- Date of manufacture and date markings
- Best before date clearly identified and visible
- Storage conditions
- Instructions for administration

Refer to UNICEF Technical requirements for pharmaceutical products

[https://www.unicef.org/supply/files/Final\\_Technical\\_Requirements\\_pharma\\_4th\\_edition\\_06.01.2012\\_AO.pdf](https://www.unicef.org/supply/files/Final_Technical_Requirements_pharma_4th_edition_06.01.2012_AO.pdf)

**Language Text:** All the packaging material, including label and patient information leaflet, must be in English & French, preferably English, French and & Arabic.

Material safety data sheet information (MSDS): required.