



PRODUCT SPECIFICATION SHEET
Vitamin D 400IU tablets, in a blister pack or bottle

Version no: 1
Material No: U357800
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General description:

Vitamin D3 400 IU tablets in a blister pack or bottle of a minimum of 30 tablets.

Technical specifications:

Tablets containing vitamin D equivalent to 200-400IU/drop of cholecalciferol in a blister pack or bottle of minimum 30 tablets.

Acceptable pharmacopoeia

Complying 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

Children older than 12 years, pregnant women and other adults: Equivalent to/not more than, 400 IU/10 mcg daily, or as directed by physician.

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

Shelf life: Minimum 24 months, preferably 36 months

The product shall retain its specifications for at least 24 months from date of manufacture when stored in dry conditions at a temperature of a minimum of 25°C, supported by real time shelf life data.

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.

Packaging and labelling: Packed in a tamper-evident bottle or blister pack containing a minimum of 30 tablets.

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

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): N/A