



PRODUCT SPECIFICATION SHEET

**Elemental Calcium 400-600mg Tablets,
Bottle / Blister of min. 120 Tablets**

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General Description

Calcium 400-600mg tablets in blister or bottle. Packs of minimum 120 tablets or capsules.

Technical specifications

Each tablet contains:

Calcium equivalent to 400-600mg elemental Calcium (as elemental calcium).

Active ingredients shall comply with one of the following Pharmacopoeias:

BP, Ph. Eur., Ph. Int., USP

Tablets shall comply with the following monograph:

BP, Ph. Eur., Ph. Int., USP Tablets

BP, Ph. Eur., Ph. Int., USP Film coated tablets

BP, USP Calcium lactate tablets

Indications

Calcium supplementation as part of the antenatal care for the prevention of preeclampsia and high blood pressure among pregnant women. Calcium supplementation is recommended for all women in their last trimester of pregnancy, particularly those at higher risk of hypertension, based on the WHO Guideline: Calcium supplementation in pregnant women

http://apps.who.int/iris/bitstream/10665/85120/1/9789241505376_eng.pdf?ua=1

Dose

Ideally up to 6 tablets daily. Dosed at 2 tablets 3 times per day.

To be taken with meals.

Preferably taken away from iron containing supplements.

Standard 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.

Statement of quality

UNICEF enforces strict quality standards starting from raw materials to movement of the finished pharmaceutical product throughout the supply chain.

Quality refers to the biological, bioavailability, chemical,

microbiological physical and stability attributes that a pharmaceutical product should maintain if it is to be deemed suitable for therapeutic or diagnostic use. The term is also used to convey the properties of identity, strength, purity, efficacy and safety.

Packaging and labelling

Packed in a tamper-evident bottle or blister pack containing a minimum of 120 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

For UNICEF packaging and labelling requirements for pharmaceuticals see the link below:

<https://www.unicef.org/supply/media/1246/file/Technical%20requirements%20for%20pharmaceutical%20and%20nutrition%20products.pdf>

Proposed additional label text

Calcium supplementation is recommended in the last trimester of pregnancy.

Storage: Store in a cool dry place, away from direct sunlight. Keep out of reach of children

Dosage: 2 tablets 3 times daily, to be taken with food, or as directed by your health care practitioner. Preferably taken away from iron supplements.