



PRODUCT SPECIFICATION SHEET

Micronutrients tabs, pregnancy/BOT-100

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1. General description

Micronutrient film coated tablets, for Pregnancy and lactating women in a bottle of 100 tablets.

Each tablet is preferably as small as possible.

2. Technical specifications

Each tablet contains

Vitamin A (RE): 800 mcg (2667 IU)
Vitamin E (dl-Alpha-Tocopheryl Acetate): 10 mg
Vitamin D (Cholecalciferol): 5 mcg (200 I.U.)
Vitamin B1 (Thiamine): 1.4 mg
Vitamin B2 (Riboflavin): 1.4 mg
Niacin (Nicotinamide): 18 mg NE
Vitamin B6 (Pyridoxine): 1.9 mg
Vitamin B12 (Cyanocobalamin): 2.6 mcg
Folic acid: 400 mcg
Vitamin C (Ascorbic acid): 70 mg
Iron: 30 mg
Zinc: 15 mg
Copper: 2 mg
Selenium: 65 mcg
Iodine: 150 mcg

API shall comply with one of the following Pharmacopoeias:

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

FPP tablets shall comply with the following monograph:

Oil- and Water-Soluble Vitamins with Minerals Tablets, USP (most recent version) and applicable General Notices and Requirements, or equivalent.

Dissolution test should be included in the product specification as per USP, BP or Eur.Ph. Unless otherwise specified in the individual monograph, the requirements are met if not less than 75% of the labelled content of iron and folic acid from the tablets is dissolved in 1 hour.

Applicable reference

1. [Vitamin and mineral requirements in human nutrition, 2nd edition \(who.int\)](#)
2. UNICEF/WHO/United Nations University multiple micronutrient supplement for pregnant and lactating women (UNIMMAP), Composition of a multi-micronutrient supplement to be used in pilot programmes among pregnant women in developing countries: report of a United Nations Children's Fund (UNICEF), World Health Organization (WHO) and United Nations University workshop
[UNICEF-WHO-multi micronutrients.pdf;jsessionid=833166B5A459286955A256B77ABE8D3D](#)

3. Therapeutic Class

Nutritional product, vitamins, and minerals

4. Standard Shelf life

24 months minimum, preferably 36 months

5. Stability data requirements:

Zone IV b as per ICH guidelines

6. Dispensing Instructions

Dispense in original container. Do not repack.

7. Packaging and labelling

A Patient Information Leaflet should be attached or enclosed in a box with each pack. Refer to *UNICEF Technical Requirements for Pharmaceutical Products* [5 \(unicef.org\)](#). Packed in a tamper-evident container of 100 tablets.

Label and leaflet should be in English and French, preferably English, French Spanish and Arabic. The label must be similar to the one shown in the appendix of the specification.

8. Child-Proof Packaging

Child resistant cap on each pack/bottle is preferred.

9. Guidelines for Use

1. WHO recommendations on antenatal care for a positive pregnancy experience. World Health Organization 2016
<http://apps.who.int/iris/bitstream/10665/250796/1/9789241549912-eng.pdf?ua=1>
2. [Nutritional interventions update: multiple micronutrient supplements during pregnancy \(who.int\)](#)

10. Items supplied with: consumer leaflet

11. Items required, but not supplied: N/A

12. Storage and transportation

Do not store or transport above 30 °C; transport between 15-25 degrees, store in tightly closed original container, protect from moisture.

13. Material Safety Data Sheet Information (MSDS)

Required/Keep out of reach and sight of children

Appendix

Pregnancy and Lactation Vitamin & Mineral Supplement
Complément vitaminique et minéral pour la grossesse et la lactation
Suplemento de vitaminas y minerales para el embarazo y la lactancia
مكمّل غذائي من الفيتامينات والمعادن للحمل والرضاعة
Provides 15 essential nutrients to support a healthy pregnancy
Apporte 15 nutriments essentiels contribuant à une grossesse saine
Aporta 15 nutrientes esenciales para contribuir a un embarazo sano
يوفر 15 عنصرًا غذائيًا أساسيًا لدعم الحمل الصحي

100 Tablets 100 comprimés 100 tabletas 100 قرص

Manufactured by:

Batch No:
Man. Date:
Exp. Date:

Useful Resources

1. Minimum stability testing reporting requirements (guidance) for stability reports- Nutritional supplements (Tablets & oral solutions)
2. Interagency finished pharmaceutical product questionnaire
3. Technical questionnaire for pharmaceutical manufacturers
4. Technical Requirements for Pharmaceutical and Nutrition Products

FOR MORE INFORMATION

CPHHQ-SD- Nutrition Supplies sd.nutritionssupplies@unicef.org

[Technical resources for nutrition products | UNICEF Supply Division](#)