



PRODUCT SPECIFICATION SHEET

Micronutrients tabs, pregnancy/BOT-100

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Material No: S1580101

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1. General description

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

Each tablet is preferably as small as possible.

2. Technical specifications

Each tablet contains

Vitamin A (R.E.): 800 mcg
Vitamin E (T. E.): 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
Vitamin B6 (Pyridoxine): 1.9 mg
Vitamin B12 (Cyanocobalamin): 2.6 mcg
Folic acid: 400 mcg
Vitamin C: 70 mg
Iron: 30 mg
Zinc: 15 mg
Copper: 2 mg
Selenium: 65 mcg
Iodine: 150 mcg

Active Pharmaceutical Ingredients (API) shall comply with at least one of the following Pharmacopoeias:

British Pharmacopoeia (BP); European Pharmacopoeia (Ph. Eur.), International Pharmacopoeia (Ph. Int.), United States Pharmacopoeia (USP), Japan Pharmacopoeia (JP)

Finished Pharmaceutical Product shall comply with the following monograph:

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

Dissolution test should be included in the supplier's finished product specification in accordance with USP, BP or Ph. Eur. If the relevant monograph does not specify otherwise, the finished

product meets the requirements if not less than 75% of the labelled content of iron and folic acid from the tablets are dissolved in 1 hour.

Applicable reference

1. [Vitamin and mineral requirements in human nutrition, 2nd edition \(who.int\)](#)
2. UNICEF/WHO/United Nations University (1999) *“United Nations International Multiple Micronutrient Antenatal Preparation (UNIMMAP):” Composition of a multi-micronutrient supplement to be used in pilot programs 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

Refer to container-closure systems in *UNICEF Technical Requirements for Pharmaceutical and Nutrition Products*: [Technical requirements for pharmaceutical and nutrition products | UNICEF Supply Division](#)

A Patient Information Leaflet should be attached or enclosed in a box with each pack. Label and leaflet should be in English and French. It is preferred to have the label and leaflet in four languages, 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

Useful Resources

1. Minimum stability testing reporting requirements (guidance) for stability reports- Nutritional supplements (Tablets & oral solutions) [Stability-Study-Format-Nutritional-Supplements_.pdf](#)
2. Interagency finished pharmaceutical product questionnaire [Interagency-finished-pharmaceutical-product-questionnaire.pdf](#)
3. Technical questionnaire for pharmaceutical manufacturers [Technical questionnaire for pharmaceutical manufacturers | UNICEF Supply Division](#)
4. Technical Requirements for Pharmaceutical and Nutrition Products [Technical requirements for pharmaceutical and nutrition products | UNICEF Supply Division](#)

Appendix: Label artwork

Pregnancy and Breastfeeding Vitamin and Mineral Supplement
Supplément vitaminique et minéral pour la grossesse et l'allaitement
Suplemento de vitaminas y minerales para el embarazo y la lactancia
مكمل فيتامينات و معادن للحمل و الرضاعة

Provides 15 essential nutrients to support a healthy pregnancy
Fournit 15 nutriments essentiels pour soutenir une grossesse saine
Aporta 15 nutrientes esenciales para favorecer un embarazo saludable
توفر 15 عنصرًا غذائيًا أساسيًا لدعم حمل صحي

Dose: One tablet per day / **Dose:** Un comprimé par jour / **Dosis:** Una tableta por día / جرعة: قرص واحد يوميًا

100 Tablets 100 Comprimés 100 Comprimidos 100 أقراص



UNIMMAP

Warning: Iron overdose can be fatal for children under 6. Keep out of reach of children. In case of overdose, seek medical help or contact poison control immediately.

Avertissement: Un surdosage en fer peut être fatal pour les enfants de moins de 6 ans. Tenir hors de portée des enfants. En cas de surdosage, consulter un médecin ou contacter immédiatement un centre antidépense.

Manufactured by / Fabriqué par / Fabricado por / تصنع بواسطة

Batch No.:
Mfg. date:
Exp. date:

Varnish Free

OPEN HERE

FOR MORE INFORMATION

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