PRODUCT SPECIFICATION SHEET

tor every child

Multiple Micronutrient Supplement (30 tablet blister pack)

Version no: 1.2.2 Material No: S1580102 Author: ARF, RK Revised by: HN, DK Date: 22.03.2022

1. General Description

Micronutrient film coated tablets, for pregnant and lactating women in a blister pack of 30.

Each tablet or capsule is preferably as small as possible.

2. Technical specifications

Each tablet contains

Vitamin A (retinol): 800 RE Vitamin E (T.E): 10 mg Vitamin D (cholecalciferol): 200 I.U. (5 mcg) 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

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.

3. Therapeutic Class

Nutritional product, vitamins, and minerals.

4. Standard Shelf life

24 months minimum, preferably 36 months.

5. Dispensing Instructions

Dispense in original container. Do not repack.

6. 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 <u>5 (unicef.org)</u>

Label and leaflet to be in English or French. A local language may be required. (see Appendix)

7. Component of a kit

No

8. 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. <u>Nutritional interventions update: multiple micronutrient supplements during pregnancy (who.int)</u>

9. Items supplied with

Consumer leaflet

10. Items required, but not supplied:

N/A

11. Shelf life

24 months minimum, preferably 36 months

12. Stability data requirements

Zone IV b as per ICH guidelines

13. 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.

14. Material Safety Data Sheet Information (MSDS)

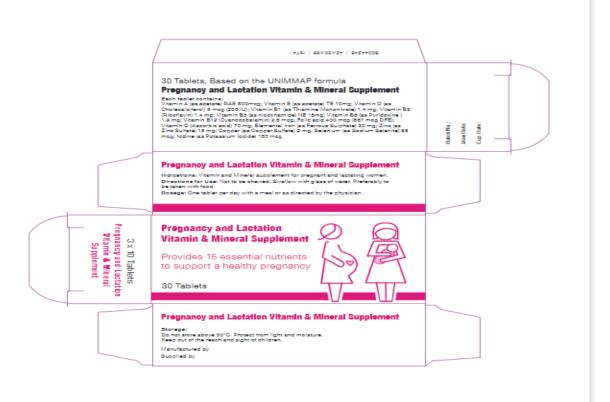
Keep out of reach and sight of children

Useful Resources

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

Appendix

Generic label artwork of MMS-blister pack box



FOR MORE INFORMATION

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

Technical resources for nutrition products | UNICEF Supply Division