

PRODUCT SPECIFICATION SHEET

Thiamine 50 mg tablets/PAC-100

Material Nr.: S0000203

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Revised by: AK, RKK, DK

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1. General description

Thiamine 50mg tabs/PAC-100

2. Technical specifications

Thiamine (hydrochloride) 50 mg, scored tablets, bottle of 100 tablets, in a nonmetallic container, protected from light.

3. Acceptable Pharmacopeias

Should comply with one of the below listed pharmacopeias

British Pharmacopoeia (BP)
United States Pharmacopoeia (USP)
European Pharmacopoeia (Ph.Eur)
International Pharmacopoeia (Ph.Int)

4. Indications

For the treatment and prevention of thiamine deficiency in adults and children.

5. Dosage, instruction for use

6. Shelf life

24 months; will prefer 36 months shelf life.

7. Storage and transportation

Do not store above 30°C. Protect from light and moisture. Keep out of the reach and sight of children.

8. Packaging and labelling

A Patient Information Leaflet should be attached or enclosed in a

Refer to UNICEF Technical requirements for pharmaceutical products <u>5 (unicef.org)</u>

Language Text: All the packaging material, including label and patient information leaflet, should be in English and French, preferably in English, French & Arabic.

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 <u>Isd.nutritionsupplies@unicef.org</u>

Technical resources for nutrition products | UNICEF Supply Division