



**PRODUCT SPECIFICATION SHEET**

Pyridoxine 25 mg tablets/Bottle PAC-100

Material Nr.: S0000202

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**1. General Description**

Pyridoxine 25 mg tabs/PAC-100

**2. Technical specifications**

Pyridoxine (hydrochloride) 25 mg tablets, bottle of 100 tablets.

**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 pyridoxine deficiency in adults and children.

**5. Guidelines for use (labelling information)**

Pyridoxine is recommended in HIV patients on isoniazid as it is a benign intervention which prevents peripheral neuropathy and other isoniazid toxicities.

The dosing of pyridoxine when administered with isoniazid preventive therapy for HIV-infected individuals is 25- 50mg daily

**6. Applicable Reference**

For general information on uses, contra-indications, precautions, dose, and adverse effects of this product, please refer to the WHO Model Formulary: [WHO model formulary for children 2010](#)

**7. Shelf life**

24 months, preferably 36 months shelf life.

**8. Storage and transportation**

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

## 9. Packaging and labelling

100 tablets packed in a tightly closed, nonmetallic container, protected from light.

Refer to UNICEF Technical requirements for pharmaceutical products [5 \(unicef.org\)](#)

A patient information leaflet (PIL) should be attached or enclosed with the packaging.

**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

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## FOR MORE INFORMATION

CPHHQ-SD- Nutrition Supplies [sd.nutritionssupplies@unicef.org](mailto:sd.nutritionssupplies@unicef.org)

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

