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.nutritiionsupplies@unicef.org

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