Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

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Pyridoxine Tablets BP 25mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains:

Pyridoxine Hydrochloride BP 25mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablets (Uncoated)

White to off white, round, flat, uncoated tablets with beveled edges and having score line on one side.

4.0 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Pyridoxine Hydrochloride is used for isoniazid-induced peripheral neuritis, idiopathic sideroblastic anaemia and Vitamin B_6 deficiency states.

4.2 Posology and Method of administration

For isoniazid-induced peripheral neuritis

Adults:	Treatment – 50mg three times daily
	Prophylaxis – Not suitable with this dosage form
Children:	This presentation is not recommended

For idiopathic sideroblastic anaemia

Adults:	100 to 400mg daily in divided doses
Children:	This presentation is not recommended

For deficiency states

Adults:	50 to 150mg daily in divided doses

Children: This presentation is not recommended

Elderly: Dosage requirements appear to be similar to those for young adults

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

If symptoms persist or worsen, seek medical advice. Do not exceed the stated dose.

4.5 Interaction with other medicinal products and other forms of interact.

Many drugs may alter the metabolism or bioavailability of pyridoxine, including isoniazid, penicillamine and oral contraceptives, which may increase the requirements for pyridoxine. Pyridoxine hydrochloride may reduce the effect of levodopa, a drug used in the treatment of Parkinsons Disease unless a dopa decarboxylase inhibitor is also given.

4.6 Pregnancy and Lactation

Data on exposed pregnancies indicate no adverse effects of pyridoxine in therapeutic doses on pregnancy or the health of the foetus or newborn child, or during lactation.

Animal studies are insufficient with respect to effects on pregnancy, embryonal/foetal development, parturition or postnatal development.

Caution should be exercised when prescribing to pregnant women.

4.7 Effects on ability to drive and use machines

Not Known

4.8 Undesirable effects

Long term administration of large doses of pyridoxine is associated with the development of severe peripheral neuritis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal

product. Healthcare professionals are asked to report any suspected adverse reactions via EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

a) Symptoms – None reported

b) Treatment – no treatment necessary.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

Pyridoxine hydrochloride is Vitamin B_6. It is converted to pyridoxal phosphate which is the co-enzyme for a variety of metabolic transformations. It is essential for human nutrition.

5.2 Pharmacokinetic Properties

Pyridoxine hydrochloride is absorbed from the gastrointestinal tract and is converted to the active forms pyridoxal phosphate and pyridoxamine phosphate. It crosses the placental barrier and appears in breast milk. It is excreted in the urine as 4-pyridoxic acid.

5.3 Preclinical Safety Data

Not applicable.

6.0 Pharmaceutical Particulars

6.1 List of Excipients

Maize Starch, Calcium Sulphate Dihydrate, Povidone k-30, Sodium methyl hydroxybenzaote, Sodium propyl hydroxy benzoate, Purified talc, Magnesium Stearate, Colloidal Anhydrous Silica, Purified Water*.

*Lost during processing

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C in a dry place. Protect from light.

6.5 Nature and contents of container

10 Tablets packed in Blister Aluminium Foil and Amber PVC Film and such 10 blisters packed in a unit carton along with package insert.

6.6 Special precautions for disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER

MEDICAMEN Biotech Limited

SP-1192 A&B, PHASE - IV,

Industrial Area,

Bhiwadi - 301 019

Distt. Alwar,

Rajasthan, India.

8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

Registration No :05445/08034/NMR/2019

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION]

Approval date :21-10-2020

10. DATE OF REVISION OF THE TEXT

July 2024