NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION & CONTROL (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

Product Name

PACEDOXIN
(Pyridoxine Tablets BP 50 mg)

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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1. Name of the medicinal product

PACEDOXIN

(Pyridoxine Tablets BP 50 mg)

2. **Qualitative and quantitative composition**

Each uncoated tablet contains:

Pyridoxine Hydrochloride BP 50 mg

3. Pharmaceutical Form

Tablet

4. Clinical Particulars

4.1 Therapeutic indications

Pyridoxine Hydrochloride is used for isoniazid-induced peripheral neuritis, idiopathic sideroblastic anaemia and Vitamin B6deficiency states.

4.2 Posology and method of administration

Dosage and 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 interaction

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 Fertility, 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

None 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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

4.9 Overdose

a) Symptoms – None reported

b) Treatment – no treatment necessary.

5 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

There are no preclinical data.

6.0 PHARMACEUTICAL EXCIPIENTS

6.1 List of excipients

Pyridoxine Hydrochloride BP
Maize Starch BP
Dibasic Calcium Phosphate BP
Lactose BP
Polyvinylpyrrolidone K-30 BP
Sodium Methylparaben BP
Sodium Propylparaben BP
Magnesium Stearate BP
Purified Talc BP
Sodium Starch Glycolate BP
Sunset Yellow Color (SUPRA) BP
Sodium Edetate BP
Purified Water BP

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precautions

Store at temperature not exceeding 30 °C. Protect from light.

6.5 Nature and contents of container

1000 tablets in a jar.

6.6 Instruction for use handling and disposal:

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

PACEDOXIN
(Pyridoxine Tablets BP 50 mg)

7. Manufacturer name

Alpa Laboratories Limited
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8. Marketing Authority

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