SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

1.1 Proprietary Name

Pyridoxine 25mg Tablet

1.2 Strength

Each tablet contains 25mg of Pyridoxine Hydrochloride

2. Qualitative and quantitative composition

2.1 Qualitative declaration

Name of Active Ingredient
Pyridoxine Hydrochloride

2.2 Quantitative declaration

Name of Active Ingredient	Quantity/tablet (mg)
Pyridoxine Hydrochloride	25mg

Excipients with known effect:

Each tablet contains Lactose 40 mg

For full list of excipients, see section 6.1

3. Pharmaceutical form

Uncoated Tablet

Product Description

White to off white circular, flat beveled edge tablet plain on both sides

4. 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 Posology

For isoniazid-induced peripheral neuritis

Adults: Treatment – 25mg six 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

Method of Administration

Tablet should be swallowed whole with a sufficient amount of liquid.

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.

Information about excipients

Harteze tablets contain lactose as one of the excipeints. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

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.

There are limited data to show the effects of Pyridoxine on fertility in both animal studies and human clinical subjects

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 authorization 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 to the relevant drug authority regulator, through the relevant platforms.

4.9 Overdose

a) Symptoms – None reported

b) Treatment – No treatment necessary.

5. Pharmacological properties

5.1 Pharmacodynamic properties

properties Therapeutic class:

Vitamin supplement ATC code:

A11HA02

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 of relevance to the prescriber, which are additional to those already included in other sections of the Summary of Product Characteristics.

6. Pharmaceutical particulars

6.1 List of excipients

Lactose BP

Maize starch BP

Magnesium stearate BP

Colloidal Anhydrous Silica BP

Potassium sorbate BP

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C

Protect from light and moisture.

6.5 Nature and contents of container

The tablets are packed into 10×10 blister packs, using a blister machine. The blister packing is done using PVC blister film and Pyridoxine Tablets printed aluminum foil.

6.6 Special precautions for disposal and other handling

Not applicable.

7 Marketing Authorization Holder

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8 Marketing Authorization Number

H1988/4764

9 Date of First Authorization/Renewal of Authorization

Date of First Authorization: 18th October, 1998
Date of Latest Renewal of Authorization: 13th May 2024

10 Date of Revision of Text

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