SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Pyridoxine hydrochloride 50 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 50 mg pyridoxine hydrochloride.

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

White to off white, circular, biconvex, film-coated tablet with breakline on one side and plain on other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Pyridoxine Hydrochloride is used for isoniazid-induced peripheral neuritis, idiopathic sideroblastic anaemia and Vitamin B6 deficiency states.

4.2 Posology and method of administration

Posology

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 the active substance(s) or to any of the excipients listed in section 6.1.

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

Pregnancy

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 respects to effects on pregnancy, embiyonal/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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

a) Symptoms - None reported

b) Treatment - no treatment necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other plain vitamin preparations, ATC code: A11HA02

Pyridoxine hydrochloride is Vitamin B6. 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

core tablet
Microcrystalline cellulose
Sodium starch glycolate, Type A
Colloidal anhydrous silica

Magnesium Stearate

film-coating
Hypromellose
Macrogol
Talc
Titanium dioxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions.

Store in the original package in order to protect from light.

6.5 Nature and contents of container

ALU-PVC/PVDC blister.

Pack sizes: 10, 14, 20, 28, 30, 40, 50, 56, 60, 70, 80, 84, 90, 100 and 112 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

Waymade PLC

Sovereign House

Miles Gray Road

Basildon, Essex, SS14 3FR

United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 06464/3129

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24/04/2025

10 DATE OF REVISION OF THE TEXT

24/04/2025