SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Pyridoxine hydrochloride 50mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50mg of pyridoxine hydrochloride.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

White to off white round shaped biconvex tablets with score line on one side and plain on the other side.

The tablet dimensions are 8.00mm x 3.60mm.

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 indicated for adults and children over 12 years old in the treatment of 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

Method of administration

Oral.

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

There are no or limited amount of data from the use of pyridoxine in pregnant women. Studies in animals have shown reproductive toxicity. Caution should be exercised when prescribing to pregnant women.

Breast-feeding

Pyridoxine is excreted in human breast milk.

A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from pyridoxine therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility

Animal studies have shown that male fertility was affected following administration of high doses of pyridoxine (see section 5.3). The relevance of these findings for human fertility is unclear.

4.7 Effects on ability to drive and use machines

No studies on the effect of this medicinal product on the ability to drive have been conducted.

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. By reporting side effects, you can help provide more information on the safety of this medicine.

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

Calcium phosphate dibasic anhydrous

Starch maize

Sodium lauryl sulfate

Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store below 25°C.

Store in the original blister in order to protect from light and moisture.

6.5 Nature and contents of container

OPA/ALU/PVC blister of 10 or 14 tablets.

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

Tablets will be packed in multiple strips of 10 tablets resulting in packs of 10, 20, 30, 40, 50, 60, 70, 80 and 90 tablets, or tablets will be packed in multiple strips of 14 tablets resulting in packs of 14, 28, 56, 84 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

Strandhaven Limited t/a Somex Pharma,
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IG3 8BS. UK.

8 MARKETING AUTHORISATION NUMBER(S)

PL 15764/0153

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25/03/2022

10 DATE OF REVISION OF THE TEXT

25/03/2022