# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Pyridoxine 50mg Tablets BP

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Pyridoxine Hydrochloride BP 50mg

## 3. PHARMACEUTICAL FORM

Oral tablet

### 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
Pyridoxine 50mg Tablets BP

### 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 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 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.

## 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 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 Hydrogen Phosphate BP
Starch Maize BP
Sodium Lauryl Sulphate BP
Magnesium Stearate BP
Purified Water BP (non-detectable in the final formulation)

## 6.2 Incompatibilities

None known

## 6.3 Shelf life

Two years

## 6.4 Special precautions for storage

Store below 25°C
Protect from light and moisture.

## 6.5 Nature and contents of container

Packs of 100 or 500 tablets contained in polypropylene securitainers or polyethylene containers.

Strip packs of opaque white or clear PVC film and 20µm aluminium foil of 10 or 14 tablets. Tablets will be packed in multiple strips of 10 tablets resulting in packs of 10, 20, 30, 40, 50, 60, 70, 80, 90 and 100 tablets, or tablets will be packed in multiple strips of 14 tablets resulting in packs of 14, 28, 56, 84 and 112 tablets.

### 6.6 Instructions for use, handling and disposal

Not applicable.

## 7 MARKETING AUTHORISATION HOLDER

Wockhardt UK Ltd
Ash Road North
Wrexham LL13 9UF
United Kingdom

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 29831/0181

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25/06/2007

## 10 DATE OF REVISION OF THE TEXT

23/04/2015