SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<Trade Name><Strength> tablets BP

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Pyridoxine hydrochloride BP 50 mg

Excipient(s) with known effect:

<Regarding the approval>

For a full list of excipients, see section 6.1.

1. PHARMACEUTICAL FORM

Oral tablets

<Regarding the approval>

1. CLINICAL PARTICULARS
   1. Therapeutic indications

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

* 1. Posology and method of administration

For isoniazid-induced peripheral neuritis

*Adults:* Treatment - 50 mg three times daily

Prophylaxis - Not suitable with this dosage form

*Children:* This presentation is not recommended

For idiopathic sideroblastic anaemia

*Adults:* 100 to 400 mg daily in divided doses

*Children:* This presentation is not recommended

For deficiency states

*Adults:* 50 to 150 mg daily in divided doses

*Children:* This presentation is not recommended

*Elderly:* Dosage requirements appear to be similar to those for young

adults pyridoxine 50 mg tablets BP

* 1. Contraindications

Hypersensitivity to any of the ingredients.

* 1. Special warnings and precautions for use

If symptoms persist or worsen, seek medical advice.

Do not exceed the stated dose.

* 1. 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.

* 1. 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 respects to effects on pregnancy, embiyonal/foetal development, parturition or postnatal development. Caution should be exercised when prescribing to pregnant women.

* 1. Effects on ability to drive and use machines

None known.

* 1. 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 Health Product Vigilance Center; HPVC, Thai FDA.

* 1. Overdose

Symptoms None reported

Treatment no treatment necessary.

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

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.

* 1. 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.

* 1. 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.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<Regarding the approval>

* 1. Incompatibilities

<Regarding the approval>

* 1. Shelf life

<Regarding the approval>

* 1. Special precautions for storage

<Regarding the approval>

* 1. Nature and contents of container

<Regarding the approval>

* 1. Special precautions for disposal

<Regarding the approval>

1. MARKETING AUTHORISATION HOLDER

<Regarding the approval>

1. MARKETING AUTHORISATION NUMBER(S)

<Regarding the approval>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<Regarding the approval>

1. DATE OF REVISION OF THE TEXT1

<Regarding the approval>