SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Pyridoxine 10mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Pyridoxine hydrochloride 10 mg equivalent to 8.2 mg pyridoxine.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
Pyridoxine 10mg tablets are plain white uncoated biconvex tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Pyridoxine is indicated for adults and children over 12 years old in the treatment of isoniazid-induced peripheral neuritis and pyridoxine deficiency states.

4.2 Posology and method of administration

Posology

Adults and children over 12 years old

Isoniazid neuropathy:

Prophylaxis 10mg daily

Treatment 50mg three times daily (Adults)

Treatment 30-50mg two to three times a day (children over 12 years)

Deficiency states:

20-50mg up to three times daily

Elderly

As for adults.

Paediatric population

Little information is available on the use of pyridoxine in children under 12 years. Doses of 4mg/Kg have been used to treat children with familial pyridoxine resistance.

Method of administration
Oral.

4.3 Contraindications

Hypersensitivity to the pyridoxine 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

Pyridoxine antagonises the therapeutic effect of levodopa when it is used without a dopa-decarboxylase inhibitor.

Larger doses of pyridoxine can cause a reduction in serum phenytoin and phenobarbitone levels in some patients.

Pyridoxine requirements have been reported to be increased by oral contraceptives, hydralazine, isoniazid, cycloserine and penicillamine.

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 (see section 5.3) Pyridoxine is not recommended during the first trimester of pregnancy.

Breastfeeding

There is insufficient information on the excretion of pyridoxine in human milk. A risk to the breastfed child cannot be excluded.

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 showed 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

Pyridoxine has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

None at recommended dosages. Large daily doses taken over a prolonged

period can cause the development of severe peripheral neuropathy.

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

4.9 Overdose

Ingestion of 2-3g may cause headache. No treatment necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pyridoxine is one of three similar compounds that may be referred to as Vitamin B6. The other two compounds are pyridoxal and pyridoxamine. Pyridoxine, converted to pyridoxal phosphate, is a co-enzyme for transamination and is involved in many metabolic processes.

5.2 Pharmacokinetic properties

Pyridoxine is readily absorbed from the gastrointestinal tract following oral administration and is converted to the active forms of pyridoxal phosphate and pyridoxamine phosphate, which are stored in the liver. The principal excretory product is 4-pyridoxic acid, which is formed by the action of hepatic aldehyde oxidase on free pyridoxal. Pyridoxine crosses the placenta and also appears in breast milk.

5.3 Preclinical safety data

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to its clinical use.

Pyridoxine causes a peripheral sensory neuropathy in embryonic chickens largely consistent with its effects in adult mammals.

The development and function of the male reproductive organs in rats were affected when high doses of pyridoxine were administered.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose

Calcium hydrogen phosphate dihydrate

Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

Available in polypropylene containers with a low density polyethylene cap containing 28 tablets.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

TOR GENERICS Ltd

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8 MARKETING AUTHORISATION NUMBER(S)

PLGB 20491/0005

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