SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

PYRIDOXINE TABLETS B.P. 50 MG

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Label claim

Each uncoated tablet contains:

Pyridoxine hydrochloride B.P. 50 mg

List of Excipients:

Crospovidone 10, Talcum, Magnesium Stearate, Microcrystalline Cellulose , Aerosil (Colloidol Silicon Dioxide).

3. PHARMACEUTICAL FORM

White coloured, circular, flat, bevelled, uncoated tablets with breakline on one side of each tablet.

4. CLINICAL PARTICULARS

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

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 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 respect to effects on pregnancy, embryonal/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.

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

Crospovidone 10, Talcum, Magnesium Stearate, Microcrystalline Cellulose , Aerosil (Colloidol Silicon Dioxide).

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in a cool dark place below 30ºC & keep out of reach of children.

6.5 Nature and contents of container

1 x 1000 tablets in plastic jar

6.6 Instructions for use and handling and disposal

No special requirements.

7. MARKETING AUTHORIZATION HOLDER

Name : **GREAT TIMEC PHARMA COMPANY LIMITED**

Address : 19B, Niger Bridge head, Housing Estate,
Fegge, Onitsha, Anambra, Nigeria

Name and address of Manufacturer*

Applicant's Name: **Nem Laboratories Pvt. Ltd.**

Address : 133 Krishna Ind. Estate, Vasai (E)
Palghar - 401210, Maharashtra-India
Tel. no. +91(250) 2390002/3

8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

NAFDAC REGN. NO.: B4-3225

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

9th October 2020

10. DATE OF REVISION OF THE TEXT

5th August 2021