New Zealand Data Sheet

APO-PYRIDOXINE

1. APO-PYRIDOXINE (50mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Name and strength of the active substance
Pyridoxine Hydrochloride 50mg

Excipient with known effect

Apo-Pyridoxine is Lactose and Gluten free.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

APO-PYRIDOXINE 50mg tablets are white, round, 8.7mm in diameter, biconvex, engraved with “APO” on one side and “PYR” over “50” on the other side. Each tablet contains 50mg pyridoxine hydrochloride and typically weighs 235mg.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The prevention and management of vitamin B6 deficiency.
Treatment of sideroblastic anaemias, homocystinuria or primary hyperoxaluria.
Vitamin B6 dependency in infants.
Pyridoxine has been widely used in premenstrual syndrome despite controversy over its effectiveness.

4.2 Dose and Method of administration

Dose

In preventing vitamin deficiencies adequate dietary intake is preferred over supplementation whenever possible. An adequate human diet in most circumstances is one containing between 1 and 2 mg vitamin B6 daily.
Doses of up to 150 mg daily have been used in general deficiency states.
Doses of up to 100mg daily from either the onset of symptoms or for 14 days prior to the start of menstruation have been used.

Method of administration

Higher doses of between 200-600 mg daily have been used in the treatment of sideroblastic anaemias, with similar doses being used to treat certain metabolic disorders such as homocystinuria or primary hyperoxaluria. Lifelong supplementation may be required to prevent reoccurrence.
Some infants require i.m. or i.v. administration for seizures due to vitamin B_6 dependency and some may require lifelong supplementation with oral doses of 2-100mg.

4.3 Contraindications

Hypersensitivity to pyridoxine hydrochloride.

4.4 Special warnings and precautions for use

Vitamin B_6 is relatively nontoxic at normal doses however long-term administration of high doses (2-6g daily) is associated with the development of severe peripheral neuropathies. Concerns exist about the possibility of neurotoxicity occurring. There have been reports of doses of 500mg daily having a toxic effect.

4.5 Interaction with other medicines and other forms of interaction

Pyridoxine increases the peripheral metabolisation of levodopa. When levodopa is combined with carbidopa this effect is prevented.

Isoniazid, cycloserine, pyrazinamide and penicillamine may antagonise the effects of pyridoxine and lead to a secondary deficiency.
It has been reported that pyridoxine decreases serum concentrations of phenobarbitone.

Patients taking oestrogens e.g. oral contraceptives have higher vitamin B_6 requirements.

4.6 Fertility, pregnancy and lactation

Pregnancy

Daily dietary requirements may increase slightly during pregnancy. No adverse effects have been reported with the use of physiologic doses during pregnancy. However the use of high doses during pregnancy has been implicated in some cases of vitamin B6 dependent syndrome in infants. Vitamin B6 crosses the placenta and also appears in breast milk.

Breast-feeding
Vitamin B6 is excreted in breast milk however no adverse effects have been reported with the use of physiologic doses during lactation.

4.7 Effects on ability to drive and use machines

Presumed to be safe or unlikely to produce and effect on the ability to drive or use machinery.

4.8 Undesirable effects

Nausea, headache, paresthesia, somnolence and low serum folic acid concentrations have been reported.

Vitamin B6 is relatively nontoxic at normal doses however long-term administration of high doses (2-6g daily) is associated with the development of severe peripheral neuropathies.

There have been reports of doses of 500mg daily having a toxic effect.

Transient dependency symptoms may occur upon withdrawal of therapy at a dose of 200mg/day for over 1 month. The significance of this is not known however for patients on large doses for long period of time withdrawal of therapy should probably be gradual.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professional are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

Sensory neuropathy can occur following long term administration of large doses. Withdrawal should be started but should probably be gradual to prevent the occurrence of transient dependency symptoms.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Vitamin preparations

ATC code: A11HA02

Uses Action

Pyridoxine (vitamin B6) is a water-soluble vitamin involved principally in amino acid metabolism, but is also involved in carbohydrate and fat metabolism. It is also required for the formation of haemoglobin.

Pyridoxine deficiency is rare in humans because of its widespread distribution in foods.

Pyridoxine deficiency may be drug induced, and inadequate utilization of pyridoxine may result from certain inborn errors of metabolism. Pyridoxine deficiency may lead to sideroblastic anaemia, dermatitis, cheilosis and neurological symptoms such as peripheral neuritis and convulsions.

5.2 Pharmacokinetic properties

Pyridoxine is readily absorbed from the gastrointestinal tract after oral administration and converted to the active forms pyridoxal phosphate and pyridoxamine phosphate. They are stored mainly in the liver where there is metabolisation to 4-pyridoxic acid and other inactive metabolites which are excreted in the urine. As the dose increases proportionally greater amounts are excreted unchanged in the urine. Vitamin B6 crosses the placenta and also appears in breast milk.

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Apo –Pyridoxine 50mg tablet contains the following excipients:

- Microcrystalline Cellulose
- Croscarmellose sodium
- Calcium hydrogen phosphate
- Aerosil
- Magnesium Stearate

Apo-Pyridoxine is Lactose and Gluten free.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Apo- Pyridoxine has a shelf like of 48 months from the date of manufacture.

6.4 Special Precautions

Store below 30°C

Protect from heat, light and moisture. Keep the container tightly closed.

6.5 Nature and contents of container

APO-Pyridoxine 50mg tablets: HDPE Bottles of 100 or 500 tablets

Not all pack sizes maybe marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

General Sale Medicine

8. SPONSOR

Apotex NZ Ltd.
32 Hillside Road
Glenfield
AUCKLAND 0627

Telephone: (09) 444 2073

Fax: (09) 444 2951

E-mail: NZcustomerservice@apotex.com

9. DATE OF FIRST APPROVAL

31 December 1969

10. DATE OF REVISION OF THE TEXT

02 March 2017

Summary Table of Changes

Section changed	Summary of new information
Whole data sheet	Reformatted as per Medsafe new data sheet. Removal of references to 25mg and 100mg strengths as the approval has lapsed
6.1	Additional information as per Medsafe requirements