

## PRODUCT LITERATURE

### ARABION B6 TABLET 10 MG

Each tablet contains:

Pyridoxine Hydrochloride 10 mg

#### Preservative:

Sodium Benzoate BP 0.1%w/w

#### Description

Round, white coloured tablet.

#### Pharmacodynamics 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.

#### 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.

#### Indication

Vitamin B6 deficiencies.

#### Route of administration

Oral

#### Recommended Dose

As prescribed by physician.

#### Contraindication

Hypersensitivity to the pyridoxine

#### Warning and Precautions

If symptoms persist or worsen, seek medical advice. Do not exceed the stated dose.

#### Interactions with Other Medicament

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.

#### 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.

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. The relevance of these findings for human fertility is unclear.

#### Side Effects

None at recommended dosages. Large daily doses taken over a prolonged period can cause the development of severe peripheral neuropathy.

#### Symptoms and Treatment of Overdose

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

#### Packing

Packed in plastic container of 30's and 100's tablets.

#### Storage Conditions

Store below 30°C in a dry place, protected from direct light.

Keep away from reach of children.

#### Expiry Date

2 years from date of manufacture

#### Name and Address of Product Registration Holder/ Distributor:

ZONTRON PHARMACEUTICALS SDN.BHD. (445695-T)

Lot 10 & 11, PERDA Industrial Park,

Lorong IKS Simpang Ampat B,

14100 Simpang Ampat, S.P.S.,

Pulau Pinang, Malaysia

#### Name and Address of Manufacturer:

TERAPUTICS SDN. BHD. (590500-W)

Lot 10 & 11, PERDA Industrial Park,

Lorong IKS Simpang Ampat B,

14100 Simpang Ampat, S.P.S.,

Pulau Pinang, Malaysia

#### Malaysian Drug Registration No. :

MAL19940196XCZ

#### Date of Revision:

07/11/2019