VITABION TABLET

Thiamine mononitrate (B1)/Pyridoxine hydrochloride (B6)/Cyanocobalamin (B12) (100mg/200mg/200 mcg)

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What Vitabion is used for

It is used in people who have nerve disorders and deficiencies or raised requirement of Vitamin B1, B6, B12. This could be due to complications from diseases such as diabetes and the damage of nerves in alcoholics. This also could include inflammation, degeneration or low back pain and other discomforting symptoms.

How Vitabion works

Vitabion is a combination of three essential vitamins (B1, B6 and B12) for nerve in high dosage.

Before you use Vitabion

- When you must not use it

Do not take Vitabion if you:

- are hypersensitive (allergic) to any of the active substances or to any of the other ingredients of Vitabion
- are with Leber's disease (an inherited form of vision loss)
- have Wernicke's encephalopathy (a neurological disease)
- have megaloblastic anaemia (blood disorder) of pregnancy

Pregnancy and lactation
Do not take Vitabion if you are pregnant, trying to get pregnant or think you may be pregnant.

All active ingredients are found in the breast milk. Do not take Vitabion if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Before taking Vitabion, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-

existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the medicine.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines obtained without prescription from pharmacy, supermarket, or health food shop.

Tell your doctor or pharmacist if you are taking any of the following:

- Cycloserine, Ethionamide, Isoniazid (antibiotic for tuberculosis)
- Penicillamine (to remove excess copper from the body)
- Hydralazine, methyldopa (for high blood pressure)
- Immunospppresants such as Azathioprine, Chlorambucil, corticosteroids, corticotrophin (ACTH), Cyclophosphamide, Cyclosporine, Mercaptopurine
- Estrogen and estrogen-containing contraceptives
- Levodopa (for Parkinson's disease)
- Aminoglycosides, Chloramphenicol (antibiotic)
- Aminosalicylic acid (pain killer)
- Anticonvulsants (for epilepsy)
- Biguanides (for diabetes)
- Cholestyramine (for high cholesterol)
- Cimetidine (for gastric pain)
- Colchicine (for gout)
- Potassium salts (potassium supplement)

How to use Vitabion

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Take one tablet three times daily or as directed by physician.

When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking *Vitabion* for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Vitabion*.

Tell your doctor immediately if you become pregnant while taking this medication.

- <u>Things you must not do</u> Do not stop taking the medicine

unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give *Vitabion* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Taking large dose of vitamin B6 in long term may cause severe nerve damage.

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Driving and using machines
If the tablets make you feel sick,
dizzy or tired, or give you a
headache, do not drive or use
machines and contact your doctor
immediately.

Side effects

Like all medicines, this medicine can cause side effect, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Side effects of each vitamin are as below which is rare:

<u>Thiamine:</u> Anaphylactic reaction (coughing, difficulty in swallowing, hives, itching of skin, swelling of face, lips or eyelids, wheezing or difficulty in breathing) usually after a large dose into the vein.

<u>Pyridoxine</u>: High doses taken for several months have caused severe loss of feeling, especially in the hands and feets, progressing from unstable gait and numb feet to numbness to clumsiness of hands.

<u>Cyanocobalamin:</u> Anaphylactic reaction (skin rash, itching, wheezing)

Other less frequent side effects include diarrhea.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI).

Storage and Disposal of Vitabion

Storage

Keep medicines out of reach of children.

Store at a temperature not more than 30°C .

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will you protect the environment.

Product Description

- What it looks like

Peach colour, round, biconvex, bevelled on both sides, film coated tablet with engraved manufacturer's logo on one side and plain on the other

- Ingredients

- Active ingredients:
 Thiamine mononitrate (B1),
 Pyridoxine hydrochloride (B6),
 Cyanocobalamin (B12)
- Inactive ingredients: Dibasic calcium phosphate, Povidone (PVP K-30), Povidone (PVP K-90), Propylene glycol, cider Cherry flavor, Edetate disodium, Purified water, Isopropyl alcohol, Colloidal silicon dioxide, Sodium starch glycolate, Glyceryl behenate, Magnesium stearate, Opadry II 85G18490 White, Lake Ponceau 4R (C.I. No. 16255), Lake Sunset yellow (C.I. No. 15985), Simethicone emulsion Eudragit E 100, Titanium dioxide, Talc, Polyethylene glycol (PEG Isopropyl 6000), alcohol and Acetone

- MAL Number: - MAL07050202XZ

Manufacturer

Unison Laboratories Co., Ltd. 39 Moo 4, Klong Udomcholjorn, Muang Chachoengsao, Chachoengsao 24000 Thailand

Product Registration Holder

Medispec (M) Sdn. Bhd. No. 55 & 57, Lorong Sempadan 2 (Off Boundary Road) 11400 Ayer Itam, Penang, Malaysia

Date of Revision

6.3.2018

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