

UNINEURO FILM-COATED TABLET

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

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What UniNeuro is used for

For disorder of the nervous system, involving damages that affect nerves or group of nerves and multiple nerves. This include:

- nerve damage caused by long term high blood sugar,
- nerve damage results from excessive drinking of alcohol,
- nerve damage caused by drug ingestion, drug or chemical abuse,
- inflammation of a nerve and pain in the one or more nerves especially cervical syndrome, shoulder arm syndrome, low back pain, numbness, and/or weakness that radiate from lower back to the buttocks and leg.

Also used for deficiency and raised requirement of vitamin B1, B6 and B12.

How UniNeuro works

UniNeuro contains 3 types of Vitamin B which are Pyridoxine Hydrochloride (B6), Cyanocobalamin (B12) and Thiamine Hydrochloride (B1). These are the vitamin B which will replenish the deficiency in the body.

Before you use UniNeuro

-When you must not use it

It should not be given to:

- individual known to be hypersensitive to any of the components of the formulation.
- children and adolescents (less than 18 years old) due to their high active substance content.

-Before you start to use it

Pregnancy and lactation

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or are breastfeeding.

Pregnancy

The possible risk for human beings is not known. The treating physician should decide about the use of this product during pregnancy after carefully weighing the risk-to-benefit ratio.

Breast-feeding

Vitamins B1, B6 and B12 are secreted into human breast milk. The advantages of breastfeeding for the infant should be carefully weighed against the therapeutic benefit for the women in order to decide to either discontinue breast-feeding or therapy.

-Taking other medicines

Inform your doctor or pharmacist before taking this medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and UniNeuro may interfere with each other. They may be affected by it or may affect how well it works.

- Thiamine is inactivated by 5-fluorouracil
- Antacids diminish the absorption of thiamine.
- Loop diuretics, e.g. furosemide that inhibit tubular reabsorption may cause increased excretion of thiamine in long-term therapy and, thus, lowering of the thiamine serum level.
- If taken simultaneously with L-dopa, vitamin B6 can lessen the dopa effect.
- The simultaneous administration of pyridoxine antagonists (e.g. isoniazide (INH), hydralazine, Dpenicillamine or cycloserine) may decrease the efficacy of vitamin B6 (pyridoxine).
- Long term use of acid-lowering agents may lead to vitamin B12 deficiency.
- Alcohol and black tea diminish the absorption of thiamine.
- Beverages containing sulphite (e.g. wine) enhance thiamine degradation.

How to use UniNeuro

-How much to use

Always use UniNeuro exactly as your doctor has prescribed. You should check with your doctor or pharmacist if in doubt.

The usual dose:

One coated tablet once daily. In individual cases, the dose may be increased to one coated tablet 3 times daily.

The coated tablets are to be swallowed whole with plenty of liquid after meals.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Continue taking UniNeuro as your doctor recommended. If symptoms persist, consult your doctor.

The physician in charge should decide on the duration of administration. After a maximum period of four weeks, it should be decided whether to reduce the dose.

If symptoms of peripheral sensory neuropathy (paraesthesia) occur, the dosage should be reviewed and treatment with the medicinal product discontinued, if necessary. Regular monitoring is recommended under long-term treatment.

-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.

Taking too much UniNeuro may cause:

- Very high doses of Vitamin B1 (over 10 g) have a ganglion-blocking effect.
- Long-term intake (> 6-12 months) of a daily dosage > 50 mg vitamin B6 may, however, cause peripheral sensory neuropathy and other sensorial neuropathy syndromes.

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- High parenteral dose of Vitamin B12 may cause allergic reactions, eczematous skin changes and a benign form of acne.

While you are using UniNeuro

-Things you must do

- Tell all the doctors, dentists and pharmacists treating you that you are taking UniNeuro.
- Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

- Do not take more than the recommended dose unless your pharmacist or doctor tells you.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give UniNeuro to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

UniNeuro do not affect the capability to drive a vehicle or to operate machinery.

Side effects

Like all medicines, UniNeuro can cause side effects, although not everybody gets them.

If side effects persist, do not take the medicine and refer to the doctor.

Tell your doctor if you notice any of the following side effects or notice any other side effects:

- Nervous system disorders: Long-term intake (> 6-12 months) of a daily dosage > 50 mg vitamin B6 may cause peripheral sensory neuropathy.
- Gastrointestinal disorders: nausea, vomiting, diarrhoea and abdominal pain.
- Immune system disorders: Hypersensitivity reactions such as sweating, tachycardia (fast heartbeat) and skin reactions like itching and urticaria (hives).
- Renal and urinary disorders: Chromaturia ("reddish urine", appeared during the first 8 hours after an administration and typically resolves within 48 hours).

National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of UniNeuro

-Storage

Store below 30°C. Protect from light and moisture.

Keep medicine out of reach of children.

-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 help to protect the environment.

Product description

-What it looks like

White to off white color film coated, round tablet.

-Ingredients

-Active ingredient

Pyridoxine Hydrochloride (B6), Thiamine Hydrochloride (B1) and Cyanocobalamin (B12)

-Inactive ingredients

Lactose monohydrate, Microcrystalline cellulose, Povidone K25, Chloroform Spirit, Magnesium stearate and Corn starch.

-MAL number

Manufactured by and Product Registration Holder

KCK Pharmaceutical Industries Sdn. Bhd.

Plot 61, Bayan Lepas Industrial Park Phase 4, Lintang Bayan Lepas 1, 11900 Bayan Lepas, Pulau Pinang, Malaysia.

Date of revision

19/05/2022

Serial Number

NPRA(R2)22/039

You may report any side effects or adverse drug reactions directly to the