RE-B FORTE TABLET

Thiamine mononitrate (B1)/Pyridoxine hydrochloride (B6)/Cyanocobalamin (B12) (250mg/250mg/1mg)

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What Re-B Forte is used for

Re-B Forte is used in the complex treatment of the following nerve disorders including inflammation of nerve or nerve pain or change in metabolic and nerve due to pregnancy and oral contraceptive.

How Re-B Forte works

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

Before you use Re-B Forte

- When you must not use it
- Do not take Re-B Forte if you:
- are hypersensitive (allergic) to any of the active substances or to any of the other ingredients of Re-B Forte
- have megaloblastic anaemia (blood disorder) of pregnancy

Pregnancy and lactation
All active ingredients are found in the breast milk. Do not take Re-B Forte if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Re-B Forte if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Before taking Re-B Forte, your doctor need to exclude any degeneration of spinal cord and damage in nerve of the eyes.

- 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:

- Levodopa (for Parkinson's disease)
- Phenobarbital, phenytoin (for epilepsy)
- Loop diuretics (water pills)
- Hydralazine (for high blood pressure)
- isoniazid, (antibiotic for tuberculosis)
- penicillamine (to remove excess copper from the body)
- · Oral contraceptive
- Neomycin (antibiotic)
- aminosalicylic acid (pain killer)
- metformin (for diabetes)
- potassium chloride (potassium supplement)
- colchicine (for gout)
- Proton pump inhibitor (omeprazole, lansoprazole, pantoprazole, rabeprazole) and histamine H2 antagonist for gastic pain
- Cholestyramine, colestipol (for high cholesterol)

How to use Re-B Forte

- 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.

Therapeutic Dose: 2 - 3 tablets daily

for 7 - 10 days.

Maintenance Dose: 1 Tablet daily.

- When to use it

Use as directed by your doctor or pharmacist.

Re-B Forte should be swallowed whole, during or immediately after meals. Do not take the tablets on an empty stomach

- How long to use it

Continue taking Re-B Forte 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.

- <u>If you use too much (overdose)</u>

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

- <u>Things you must do</u>
Take your medicine executives

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Re-B Forte.

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

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

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 Re-B Forte to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

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.

Long term use of large doses of pyridoxine is associated with the development of severe nerve damage.

Avoid food that contains sulfites, tea, coffee and decaffeinated coffee as it may inactivate thiamine.

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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 Re-B Forte *Storage*

Keep medicines out of reach of children.

Store at temperature of 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

Scarlet, round, biconvex, bevelled on both sides, film coated tablet with engraved F on one side and plain on the other

- Ingredients

- Active ingredients:
Thiamine mononitrate (B1),
Pyridoxine hydrochloride (B6),
Cyanocobalamin (B12)

- Inactive ingredients:

Calcium phosphate dihydrate, Povidone (PVP K-90), Propylene glycol, Cherry cider 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 Carmoisine (C.I. No. 14720), Isopropyl alcohol, Simethicone emulsion 30%, Eudragit E 100, Titanium dioxide, Polyethylene glycol (PEG 6000), Isopropyl alcohol and Acetone

- <u>MAL Number: -</u> MAL07061575XZ

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

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23.2.2018

Serial number

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