

Biological Therapies B-Dose Forte 2.5 mL Injection

Vitamin B Complex for Intramuscular Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Biological Therapies B-Dose Forte 2.5 mL Injection. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of administering B-Dose Forte Injection against the benefits they expect it will have for you.

If you have any concerns about the administration of this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Biological Therapies B-Dose Forte Injection is used for

B-Dose Forte 2.5 mL Injection contains the Vitamins B1, B2, B3, B5, B6 and B12 as the following active ingredients:

B1 - Thiamine hydrochloride,
B2 - Riboflavine sodium phosphate,
B3 - Nicotinamide,
B5 - Dexpanthenol,
B6 - Pyridoxine hydrochloride,
B12 - Cyanocobalamin.

These B vitamins are required by the body for normal metabolic processes in your cells, including the production of energy. Different

metabolic processes need several of these B vitamins at the same time. Deficiencies of one, some or all of these vitamins in your cells can have serious consequences for your health.

Vitamin B deficiencies:

Vitamin B deficiencies may occur as a result of a diet deficient in B vitamins, malnutrition, or changes to the gastrointestinal tract which slow or prevent the absorption of B vitamins (e.g. abdominal surgery or some diseases of the gastrointestinal tract).

A specific deficiency of vitamin B1 (thiamine) may cause the disease beriberi.

A specific deficiency of vitamin B3 (niacin) may cause the disease pellagra.

A specific deficiency of vitamin B12 (cobalamin) may cause the disease pernicious anaemia.

Some of the B vitamins need other B vitamins to work properly.

Your doctor may prescribe B-Dose Forte Injection to treat specific vitamin B deficiencies, or to raise the levels of B vitamins in your body.

When administration by mouth is not feasible or appropriate:

Your doctor may decide that B-Dose Forte Injection is the best way for you to take B vitamins.

Debilitated or elderly patients where the diet is inadequate:

Confinement to bed, debility or old age may lead to an inadequate diet.

In these cases, vitamin B deficiencies may occur.

Your doctor may prescribe B-Dose Forte to supplement B vitamins missing in your diet.

Malnutrition resulting from alcoholism:

Alcoholism can lead to a diet deficient in B vitamins. The normal metabolism of alcohol in your liver also requires B vitamins, especially thiamine. Thiamine may be prescribed to treat Wernicke's encephalopathy, a disorder caused by thiamine deficiency in alcoholism.

B-Dose Forte Injection contains a high dose of thiamine and may be prescribed by your doctor to help the effects of alcoholism.

Peripheral neuritis and Carpal tunnel syndrome:

This means nerve pain, usually in the arms or hands, legs or feet (the peripheral parts). Many of the B vitamins are important for the normal functioning of the nervous system. Long-term alcoholism, beriberi, pellagra or long-term gastrointestinal disease may lead to B vitamin deficiencies and peripheral nerve pain.

Carpal tunnel syndrome and its symptoms may be relieved by the administration of vitamin B6 (pyridoxine). Carpal tunnel syndrome symptoms include pain in the hands and wrists, weakness of the hands and loss of grip strength, and coldness of the hands and fingers.

Your doctor may prescribe B-Dose Forte Injection to treat peripheral nerve pain or carpal tunnel syndrome.

Pernicious anaemia:

Anaemia occurs when red blood cells cannot carry sufficient oxygen to meet the requirements of the body's cells. This may be due to a deficiency of oxygen, lack of ability of red blood cells to bind oxygen, or some defect of red blood cells.

Vitamin B12 is needed to make red blood cells grow correctly, without it the red blood cells become large and less effective. This is a type of anaemia called megaloblastic (large cells) anaemia. Megaloblastic anaemia may also be caused by a folate (folic acid) deficiency. The "pernicious" part is because prolonged Vitamin B12 deficit can also lead to damage to the nervous system. The combination of nervous system damage and anaemia is called Pernicious Anaemia.

Symptoms of pernicious anaemia include tiredness, breathlessness, lack of energy and different sensations of the nervous system, such as pins and needles and loss of strength.

B-Dose Forte may be prescribed to help with the symptoms of pernicious anaemia, or for megaloblastic anaemia if Vitamin B12 deficiency is the diagnosed cause.

Your doctor may have prescribed B-Dose Forte Injection for another reason.

Ask your doctor if you have any questions about why B-Dose Forte Injection has been prescribed for you.

B-Dose Forte Injection is not addictive.

B-Dose Forte Injection is only available from a medical practitioner.

Before you are given Biological Therapies B-Dose Forte Injection

When you must not be given it:

Do not have B-Dose Forte Injection administered if:

- **you have a known allergy to B vitamins or any of the ingredients listed at the end of this leaflet**

Symptoms of an allergic reaction may include skin rash; itchiness; shortness of breath; swelling of the face, lips, mouth or throat.

- **you are taking high dose B vitamins**
B-Dose Forte Injection should not be administered if you have high levels of B vitamins in your body from other sources, such as high dose vitamin supplements.
- **you are a haemophiliac**
Dexpanthenol, the form of vitamin B5 used in B-Dose Forte Injection should not be used if you have haemophilia.
- **you have mechanical intestinal obstruction (ileus)**
Dexpanthenol, the form of vitamin B5 used in B-Dose Forte Injection is often used to treat ileus (lack of forward movement of intestinal contents), but should not be used if you have ileus due to a mechanical intestinal obstruction (something stuck in there).
- **you are pregnant and are diagnosed with megaloblastic anaemia**
Cobalamins can mask the effects of megaloblastic anaemia caused by folate deficiency. Folate deficiency in pregnancy is a risk for birth defects in your baby. You must have Vitamin B12 deficiency confirmed by blood tests before using B-Dose Forte Injection to treat megaloblastic anaemia.

- **the solution in the bottle is not clear or contains particles.**
- **the packaging is torn or shows signs of tampering**
- **the expiry date on the pack has passed**
If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should be given B-Dose Forte Injection, talk to your doctor.

Before you have it injected:

Your doctor may test if you have an allergy to B-Dose Forte by injecting a small amount under your skin

If you have any of the following medical illnesses or conditions, you must tell your doctor. Your doctor will discuss the risks and benefits of using B-Dose Forte Injection if you have any of these illnesses or conditions.

- **Tell your doctor if you have had an allergy to any of the ingredients listed at the end of this leaflet**
- **Tell your doctor if you have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes**
- **Tell your doctor if you are pregnant or intending to become pregnant**
There is an increased need for some B vitamins during pregnancy. It is recommended that you and your doctor discuss your requirements during pregnancy and the possible risks and benefits of using B-Dose Forte Injection during pregnancy.
- **Tell your doctor if you are breastfeeding or are intending to breastfeed**
There is an increased need for some B vitamins during breastfeeding. It is recommended that you and your doctor discuss your requirements during

breastfeeding and the possible risks and benefits of using B-Dose Forte Injection during breastfeeding.

If you have not told your doctor about any of these conditions, tell them before you have B-Dose Forte Injected.

If Taking Other Medicines:

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

Some medicines and B-Dose Forte Injection may interfere with each other. These include:

- Other Vitamin and Mineral Supplements
- Levodopa
- oestrogen containing medicines, including oral contraceptives (the pill)
- immunosuppressants, such as azathioprine
- some antiepileptic drugs such as phenobarbitone and phenytoin
- hydralazine
- some drugs used to treat infections, such as isoniazid, penicillamine, cycloserine and pyrazinamide.

These medicines may be affected by B-Dose Forte Injection, or affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information about medicines to be careful with, use correctly or to avoid while you are being treated with B-Dose Forte.

How Biological Therapies B-Dose Forte Injection is given

B-Dose Forte Injection must only be given by a doctor or nurse.

B-Dose Forte Injection will be injected intramuscularly (into the buttock muscle) by your doctor.

How much is given:

Your doctor will tell you how much B-Dose Forte Injection will need to be given and for how long it is to be given. This is determined by many factors including your body weight and your medical condition. The usual dose is 2.5mL by slow intramuscular injection.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

How long to use it:

Each person will respond differently to B-Dose Forte Injection.

Treatment times will differ depending on the reason for prescribing B-Dose Forte Injection.

Typically, treatment will be once each week for 2-6 weeks. Your doctor will tell you how long you should take B-Dose Forte Injection for.

If you forget an appointment or need to change an appointment:

You will need to make another appointment as soon as possible.

If you are not sure what to do, contact your doctor or pharmacist as soon as possible.

If too much is given (overdose):

Your doctor should be the only person to inject B-Dose Forte, so an overdose is not likely to occur.

But if you think that you or anyone else may have been given too much B-Dose Forte Injection immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) or go to accident and emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are being given Biological Therapies B-Dose Forte Injection

Things you must do:

- **Tell all doctors, dentists and pharmacists who are treating you that you are being treated with B-Dose Forte Injection.**
- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with B-Dose Forte Injection.**
- **If you need to have any urine or blood tests tell your doctor that you are being given B-Dose Forte Injection. B-Dose Forte Injection may affect the results of some of these tests.**
- **Tell your doctor if you become pregnant while being treated with B-Dose Forte Injection.**
- **Tell your doctor if you feel that giving B-Dose Forte Injection is not helping your condition.**

Be sure to keep all appointments with your doctor so that your progress can be checked.

Things you must not do:

- **Do not attempt to inject B-Dose Forte Injection yourself.**
- **Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting a pharmacist.**

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given or treated with B-Dose Forte Injection.

B-Dose Forte Injection helps most people but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or nurse as soon as possible if you notice any of the following and they worry you:

- Skin irritation and/or pain around the area of injection
- Bruising around the area of injection
- Mild nausea, vomiting, abdominal pain or loss of appetite
- Headache or sleepiness
- Numbness in the hands or feet, clumsiness or difficulty walking
- Hives
- Heartburn
- Fatigue
- Sore throat

These are usually mild side effects of using B-Dose Forte, but may be serious.

If any of the following happen, stop taking B-Dose Forte and tell your doctor immediately, or go to accident and emergency at your nearest hospital:

- severe allergic reaction which may include skin rash, itching, nausea, sweating, a feeling of warmth, tingling, weakness, tightness of the throat, pain in the chest, fast heart beat, difficulty breathing, faintness or swelling of the lips, face, tongue, throat, hands or feet. Severe pain or inflammation of the feet, knees, hands, or elbows

- sneezing
- severe rash
- temporary itchiness
- blue discolouration of the skin
- bleeding
- prolonged stomach pain
- severe dizziness or drowsiness
- muscular paralysis
- low blood pressure
- prolonged nausea or vomiting
- Restlessness
- Scaling of the facial skin
- Inability to focus eyes

These are serious side effects. You may need urgent medical attention or hospitalisation.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects.

You should not experience any of them.

How to Store Biological Therapies B-Dose Forte Injection

Store at 2°C to 8°C. (Refrigerate. Do not freeze). Protect from light.

Keep out of reach of children.

This product is for SINGLE USE in one patient on one occasion only. It will be used once only and then it will be discarded. It must never be stored after it is opened, nor used for more than one person.

Product Description

What it looks like:

Biological Therapies B-Dose Forte Injection is a clear amber colour, contained in an amber glass vial sealed with a rubber stopper and an aluminium cap.

This medicine may be available in 4 pack sizes:

1 x 2.5 mL vial.

3 x 2.5 mL vials.

5 x 2.5 mL vials.

6 x 2.5mL vials.

Ingredients per vial:

Active Ingredient:

B1 Thiamine hydrochloride 250 mg

B2 Riboflavine sodium phosphate 5 mg

B3 Nicotinamide 50 mg

B5 Dexpanthenol 50 mg

B6 Pyridoxine hydrochloride 100 mg

B12 Cyanocobalamin 1 mg

Other Ingredients

Disodium Edetate

Benzyl alcohol

Water for Injections.

Supplier

Biological Therapies B-Dose Forte 2.5 mL Injection is supplied and manufactured in Australia by:

Biological Therapies

A Division of Orthomolecular Medisearch Laboratories Pty Ltd.

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