

Biological Therapies B-Dose 2 mL Injection

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given this medicine?

This medicine contains the vitamins B1, B2, B3, B5, B6 and B12 as the following active ingredients: Thiamine hydrochloride (B1), Riboflavine sodium phosphate (B2), Nicotinamide (B3), Dexpanthenol (B5), Pyridoxine hydrochloride (B6), and Cyanocobalamin (B12). It is used for the prevention and treatment of specific vitamin B deficiencies. For more information, see Section [1. Why am I being given this medicine?](#) in the full CMI.

2. What should I know before I am given this medicine?

Do not use if you have ever had an allergic reaction to this medicine or any of the ingredients listed at the end of the CMI. You should not be given this medicine if you are pregnant and are diagnosed with megaloblastic anaemia, if you are a haemophiliac or if you have mechanical intestinal obstruction (ileus).

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given this medicine?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with B-Dose 2 mL Injection and affect how it works. You should not be given B-Dose Injection if you are taking high dose vitamin B vitamins.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is this medicine given to me?

This medicine is given as an injection, intramuscularly (into the buttock muscle). This medicine must only be given by a doctor or nurse. The amount given depends on many factors including your body weight and medical condition. The usual dose given is 2 mL weekly for 2 to 6 weeks.

More instructions can be found in Section [4. How is this medicine given to me?](#) in the full CMI.

5. What should I know while being given this medicine?

Things you must do	<ul style="list-style-type: none">Remind or tell any doctor, surgeon, anaesthetist, dentist or pharmacist you visit that you are being treated with B-Dose Injection.Tell your doctor if you feel that giving this medicine is not helping your condition.Keep all of your doctor's appointments so that your progress can be checked.
Things you must not do	<ul style="list-style-type: none">Do not attempt to inject this medicine yourself.Do not take any other medicines without first telling your doctor or consulting a pharmacist.Do not give this medicine to anyone else, even if they have the same condition as you.
Looking after your medicine	<ul style="list-style-type: none">This medicine is usually stored in the doctor's surgery or clinic, or at the pharmacy, in a cool dry place, where the temperature stays below 25°C and children cannot reach it. Each vial is for SINGLE USE in one patient on one occasion only.

For more information, see Section [5. What should I know while being given this medicine?](#) in the full CMI.

6. Are there any side effects?

The more common side effects of this medicine are skin irritation, pain or bruising the injection site, mild nausea or vomiting, headaches, numbness in hands or feet, hives, heartburn, fatigue, or sore throat. Serious side effects include severe allergic reactions, 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 and inability to focus eyes.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Biological Therapies B-Dose 2 mL Injection

Active ingredient(s): *Thiamine hydrochloride (B1), Riboflavine sodium phosphate (B2), Nicotinamide (B3), Dexpanthenol (B5), Pyridoxine hydrochloride (B6), Cyanocobalamin (B12).*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Biological Therapies B-Dose 2 mL Injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using B-Dose 2 mL Injection.**

Where to find information in this leaflet:

- [1. Why am I being given this medicine?](#)
- [2. What should I know before I am given this medicine?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is this medicine given to me?](#)
- [5. What should I know while being given this medicine?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given this medicine?

B-Dose 2 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 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 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 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.

Peripheral neuritis and Carpal tunnel syndrome:

Peripheral neuritis 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 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 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 Injection for another reason.

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

B-Dose Injection is not addictive.

2. What should I know before I am given this medicine?

Warnings

You must not be given this medicine if:

- **You are allergic to B vitamins, or any of the ingredients listed at the end of this leaflet.** Always check the ingredients to make sure you can use this medicine.
- **You must not be given this medicine if you are taking high dose B vitamins.** This medicine should not be given to you if you have high levels of B vitamins in your body from other sources, such as high dose vitamin supplements.
- **You must not be given this medicine if you are a haemophiliac.** Dexpanthenol, the form of vitamin B5 used in B-Dose Injection should not be used if you have haemophilia.
- **You must not be given this medicine if you have mechanical intestinal obstruction (ileus)** Dexpanthenol, the form of vitamin B5 used in B-Dose 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 must not be given this medicine if 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 Injection to treat megaloblastic anaemia.

- **You must not be given this medicine if the solution in the vial is not clear or contains particles.**
- **If you are not sure whether you should be given this medicine, talk to your doctor.**

Check with your doctor if you:

- Are pregnant and are diagnosed with megaloblastic anaemia.
- Have any other medical conditions.
- Take any medicines for any other condition.
- **Have had an allergy to any of the ingredients listed at the end of this leaflet.** Your doctor may test if you have an allergy to this medicine by injecting a small amount under your skin.
- **Have allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend 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 having this medicine during pregnancy.

Talk to your doctor if you are breastfeeding or intend 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 having this medicine during breastfeeding.

If you have not told your doctor about any of the above, tell them before you are given B-Dose Injection.

3. What if I am taking other medicines?

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

Some medicines may interfere with B-Dose Injection and affect how it works.

These include:

- Vitamin and Mineral Supplements
- Levodopa (a medicine used to treat Parkinson's disease)
- Oestrogen containing medicines, including oral contraceptives (the pill)
- Immunosuppressants, such as azathioprine
- Some antiepileptic drugs such as phenobarbitone and phenytoin
- Hydralazine (a medicine to treat high blood pressure)
- Some drugs used to treat infections, such as isoniazid, penicillamine, cycloserine and pyrazinamide.

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

Your doctor and pharmacist have more information about medicines to be careful with, or avoid while you are being treated with this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect B-Dose 2 mL Injection.

4. How is this medicine given to me?

This medicine must only be given by a doctor or nurse.

B-Dose 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 Injection will need to be given and for how long it will need to be given. This is determined by many factors including your body weight and your medical condition. The usual dose is 2 mL 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 is the treatment time with this medicine

Each person will respond differently to B-Dose Injection.

Treatment times will differ depending on the reason for prescribing this medicine.

Typically, treatment will be once each week for 2-6 weeks. Your doctor will let you know how long you will need to be treated with this medicine.

If you miss an appointment

If you miss an appointment, talk to your doctor and arrange 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 of this medicine is given

Your doctor should be the only person to inject B-Dose Injection, so an overdose is unlikely to occur.

If you think that you or anyone else may have been given too much B-Dose Injection you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being given this medicine?

Things you must do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with B-Dose Injection.
- Tell all doctors, dentists and pharmacists who treat you that you are being given this medicine.
- If you are about to have any urine or blood tests tell your doctor that you are being treated with this medicine. It may interfere with the results of some tests.
- Tell your doctor if you become pregnant while being treated with B-Dose Injection.
- Tell your doctor if you feel that giving B-Dose Injection is not helping your condition.
- Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

- Do not attempt to inject this medicine yourself.
- Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting a pharmacist.
- Do not use this medicine if the packaging is torn or shows signs of tampering.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how B-Dose Injection affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcoholism can lead to a diet deficient in B vitamins. The normal metabolism of alcohol in your liver also requires B vitamins.

Looking after your medicine

B-Dose 2 mL Injection is usually stored in the doctor's surgery or clinic, or at the pharmacy.

If you need to store B-Dose 2 mL Injection keep it in the original pack until it is time for it to be given. If you take the vials out of the pack they may not keep well.

Store it in a cool dry place, where the temperature stays below 25°C, away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it. A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

When to discard your medicine

Each vial 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 or used for more than one person.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any vials that are left over.

Do not use this medicine after the expiry date. If you are given this medicine after the expiry date has passed, it may not work and it may be harmful to you. If it is expired or damaged, return it to your pharmacist for disposal.

6. Are there any 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 Injection.

This medicine 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 attention if you get some of the side effects.

Do not be alarmed by the following lists. You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• 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	Speak to your doctor, nurse or pharmacist as soon as possible, if you have any of these less serious side effects and they worry you.

The above list includes the mild side effects of this medicine but could be serious.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• 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	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

The above list includes serious side effects. You may need urgent medical attention or hospitalisation.

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

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What B-Dose 2 mL Injection contains

Active ingredient (main ingredient)	Thiamine hydrochloride (B1) Riboflavine sodium phosphate (B2) Nicotinamide (B3) Dexpanthenol (B5) Pyridoxine hydrochloride (B6) Cyanocobalamin (B12)
Other ingredients (inactive ingredients)	Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

This medicine does not contain any other additives such as stabilizers or local anaesthetics.

What B-Dose 2 mL Injection looks like

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

Australian Registration Number: AUST R 22266.

This medicine may be available in 4 pack sizes:

1 x 2 mL vial

3 x 2 mL vials

5 x 2 mL vials

6 x 2 mL vials

Who distributes B-Dose 2 mL Injection

Biological Therapies

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