

# Biological Therapies Methylcobalamin 10 mg in 2 mL Injection Vitamin B 12 for Intramuscular 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 using Biological Therapies Methylcobalamin 10 mg in 2mL Injection?

Methylcobalamin 10 mg in 2 mL Injection contains the active ingredient mecobalamin (Vitamin B12). Mecobalamin is used to help with the symptoms of pernicious anaemia, or for megaloblastic anaemia if Vitamin B12 deficiency is the diagnosed cause. Methylcobalamin Injection may help to treat peripheral and diabetic neuropathies (diseases of the nerves) and may improve your symptoms. Ask your doctor if you have any questions about why Methylcobalamin Injection has been prescribed for you. For more information, see Section [1. Why am I using Biological Therapies Methylcobalamin 10 mg in 2mL Injection?](#) in the full CMI.

### 2. What should I know before I use Biological Therapies Methylcobalamin 10 mg in 2mL Injection?

Do not use if you have ever had an allergic reaction to mecobalamin or any of the ingredients listed at the end of the CMI. **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 use Biological Therapies Methylcobalamin 10 mg in 2mL Injection?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Methylcobalamin 10 mg in 2 mL Injection and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Biological Therapies Methylcobalamin 10 mg in 2mL Injection?

- Your doctor will tell you how much Methylcobalamin Injection you 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. Methylcobalamin Injection is used in one patient on one occasion only. The usual dose is 10 mg by slow intramuscular injection. Methylcobalamin 10 mg in 2 mL Injection will be injected intramuscularly (into the buttock muscle) by your doctor. More instructions can be found in Section [4. How do I use Biological Therapies Methylcobalamin 10 mg in 2mL Injection?](#) in the full CMI.

### 5. What should I know while using Biological Therapies Methylcobalamin 10 mg in 2mL Injection?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist, surgeon, anaesthetist or pharmacist that you visit that you are using Biological Therapies Methylcobalamin 10 mg in 2 mL Injection.</li><li>Tell your doctor if you feel that giving this medicine is not helping your condition.</li><li>Keep all of your doctor's appointments so that your progress can be checked.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not attempt to inject this medicine yourself.</li><li>Do not take any other medicines without first telling your doctor or consulting a pharmacist.</li><li>Do not give this medicine to anyone else, even if they have the same condition as you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>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 between 2 °C and 8 °C (Refrigerate, do not freeze) and should be protected from light.</li></ul>

For more information, see Section [5. What should I know while using Biological Therapies Methylcobalamin 10 mg in 2mL Injection?](#) in the full CMI.

### 6. Are there any side effects?

Methylcobalamin Injection may have unwanted side effects in a few people which are usually mild but may be serious. 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 Methylcobalamin 10 mg in 2 mL Injection

## Vitamin B 12 for Intramuscular Injection

Active ingredient(s): *Mecobalamin*

### Consumer Medicine Information (CMI)

This leaflet provides important information about using Biological Therapies Methylcobalamin 10 mg in 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 Methylcobalamin 10 mg in 2 mL Injection**

Where to find information in this leaflet:

- [1. Why am I using Biological Therapies Methylcobalamin 10 mg in 2mL Injection?](#)
- [2. What should I know before I use Biological Therapies Methylcobalamin 10 mg in 2mL Injection?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Biological Therapies Methylcobalamin 10 mg in 2mL Injection?](#)
- [5. What should I know while using Biological Therapies Methylcobalamin 10 mg in 2mL Injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using Biological Therapies Methylcobalamin 10 mg in 2mL Injection?

Biological Therapies Methylcobalamin 10 mg in 2 mL Injection contains the active ingredient Mecobalamin. Mecobalamin belongs to a group of vitamins called cobalamins. The cobalamins are various different forms of Vitamin B12.

Mecobalamin is used to help with the symptoms of pernicious anaemia, or for megaloblastic anaemia if Vitamin B12 deficiency is the diagnosed cause. Methylcobalamin Injection may help to treat peripheral and diabetic neuropathies and may improve your symptoms. Your doctor may prescribe Methylcobalamin Injection for another reason. Ask your doctor if you have any questions about why Methylcobalamin Injection has been prescribed for you.

### 2. What should I know before I use Biological Therapies Methylcobalamin 10 mg in 2mL Injection?

#### Warnings

Do not use Biological Therapies Methylcobalamin 10 mg in 2 mL Injection if:

- You are allergic to B vitamins, or any of the ingredients listed at the end of this leaflet.
- You are pregnant and are diagnosed with megaloblastic anaemia.
- You are breastfeeding infants
- You do not have a confirmed diagnosis that Vitamin B12 may be useful.
- The solution in the bottle is not clear or contains particles.
- The packaging is torn or shows signs of tampering.
- Always check the ingredients to make sure you can use this medicine.
- Precaution should be taken if you have low potassium and are diagnosed with pernicious anaemia.

#### Check with your doctor if you:

- Have any other medical conditions such as an allergy to any of the ingredients listed at the end of this leaflet.
- Have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.

Your doctor may test if you have an allergy to mecobalamin by injecting a small amount under your skin.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not have Methylcobalamin 10 mg in 2mL Injection administered 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 Methylcobalamin Injection to treat megaloblastic anaemia.

Women receiving Methylcobalamin 10 mg in 2mL Injection should not breastfeed.

### 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.

Your doctor or pharmacist has more information about medicines to be careful with, use correctly or to avoid while you are being treated with Methylcobalamin Injection.

**Some medicines may interfere with Biological Therapies Methylcobalamin 10 mg in 2mL Injection and affect how it works.**

- Colchicine (an anti-inflammatory used to treat gout), para-aminosalicylic acid (an antibiotic used to treat tuberculosis), and heavy alcohol intake longer than 2 weeks may lower vitamin B12 absorption.
- Oral contraceptives may reduce the amount of cyanocobalamin in your blood.
- Vitamin B12 concentrations in the blood may be reduced following administration of large and continuous doses of folic acid.
- The therapeutic response to vitamin B12 may be impaired by drugs with bone marrow suppressing effects such as chloramphenicol.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Biological Therapies Methylcobalamin 10 mg in 2mL Injection.**

#### **4. How do I use Biological Therapies Methylcobalamin 10 mg in 2mL Injection?**

##### **How much to take / use**

- Your doctor will tell you how much Methylcobalamin 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 10 mg by slow intramuscular Injection. Methylcobalamin injection is used in one patient on one occasion only.
- **Follow all directions given to you by your doctor carefully.** They may differ from the information contained in this leaflet.

##### **When to take / use Biological Therapies Methylcobalamin 10 mg in 2mL Injection**

- Methylcobalamin Injection is only available from a medical practitioner. Your doctor will determine when Methylcobalamin 10 mg in 2mL Injection is suitable.

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

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

#### **If you use too much Biological Therapies Methylcobalamin 10 mg in 2mL Injection**

Your doctor should be the only person to prescribe Methylcobalamin 10 mg in 2mL Injection, so an overdose is not likely to occur.

If you think that you have used too much Methylcobalamin 10 mg in 2mL 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 using Biological Therapies Methylcobalamin 10 mg in 2mL Injection?**

##### **Things you should do**

###### **Call your doctor straight away if you:**

- are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with Methylcobalamin Injection.
- need to have any urine or blood tests, tell your doctor that you are being given Methylcobalamin 10mg in 2mL Injection. Methylcobalamin 10 mg in 2mL Injection may affect the results of some of these tests.
- become pregnant while being treated with Methylcobalamin Injection.
- feel that giving Methylcobalamin Injection is not helping your condition.

Remind any doctor, dentist, surgeon, anaesthetist or pharmacist you visit that you are using Methylcobalamin 10 mg in 2mL Injection.

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

##### **Things you should not do**

- Do not attempt to inject Methylcobalamin 10 mg in 2mL Injection yourself.
- Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting a pharmacist.

##### **Driving or using machines**

This medicine is not expected to affect your ability to drive a car or operate machinery.

##### **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

Heavy alcohol intake longer than 2 weeks may lower vitamin B12 absorption.

### Looking after your medicine

Methylcobalamin 10 mg in 2mL Injection is usually stored in the doctor's surgery or clinic, or at the pharmacy (the following information applies to the healthcare professional).

Unopened vials of Methylcobalamin Injection are to be stored at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light.

Seal box immediately after removal of each vial and **store in a dark place.**

Keep it where young children cannot reach it.

### 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.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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
<p>Sensitivity/injection site reaction:</p> <ul style="list-style-type: none"> <li>• Skin irritation and/or pain around the area of injection</li> <li>• Bruising around the area of injection</li> <li>• Any other mild allergies</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Severe allergic reaction:</b></p> <ul style="list-style-type: none"> <li>• Skin rash</li> <li>• Itching</li> <li>• Nausea</li> <li>• Feeling of warmth</li> <li>• Tingling</li> <li>• Weakness</li> <li>• Tightness of the throat</li> <li>• Pain in the chest</li> <li>• Fast heart beat</li> </ul>	<p><b>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.</b></p>

<ul style="list-style-type: none"> <li>• Difficulty breathing</li> <li>• Faintness or swelling of the lips, face, tongue, throat, breathing tubes, hands or feet</li> <li>• Severe pain or inflammation of the feet, knees, hands, or elbows</li> </ul> <p><b>Cardiovascular:</b></p> <ul style="list-style-type: none"> <li>• Pulmonary oedema (fluid in the lungs) and heart failure early in treatment</li> <li>• Peripheral vascular thrombosis (a blood clot in a blood vessel in the arms or legs)</li> <li>• Cardiac arrest</li> <li>• Low blood pressure</li> </ul> <p><b>Nervous System:</b></p> <ul style="list-style-type: none"> <li>• Severe dizziness</li> <li>• Drowsiness</li> <li>• Muscular paralysis</li> <li>• Vision problems</li> <li>• Loss of consciousness</li> </ul> <p><b>Hematological:</b></p> <ul style="list-style-type: none"> <li>• Low potassium</li> </ul> <p><b>Gastrointestinal:</b></p> <ul style="list-style-type: none"> <li>• Mild short term diarrhea</li> <li>• Ongoing abdominal (stomach) pain that lasts a long time</li> <li>• Feeling sick (nausea) or being sick (vomiting) that lasts a long time or doesn't go away</li> </ul> <p><b>Dermatological:</b></p> <ul style="list-style-type: none"> <li>• Itching</li> <li>• Short-lasting skin rash</li> <li>• Blue discolouration of the skin</li> </ul> <p><b>Miscellaneous:</b></p> <ul style="list-style-type: none"> <li>• Feeling of swelling of entire body</li> <li>• Bleeding</li> </ul>	
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**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Administration of Methylcobalamin Injection may cause anaphylactic shock. This is a serious side effect and required immediate attention by your doctor. This side effect is rare and only occurs during injection. Other side effects not listed here may occur in some people.

### 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](http://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 Biological Therapies Methylcobalamin 10 mg in 2mL Injection contains

<b>Active ingredient (main ingredient)</b>	Mecobalamin 10 mg
<b>Other ingredients (inactive ingredients)</b>	Sodium chloride Water for injections

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

### What Biological Therapies Methylcobalamin 10 mg in 2mL Injection looks like

Biological Therapies Methylcobalamin 10 mg in 2 mL Injection is a clear bright red coloured solution. It is contained in an amber glass vial sealed with a rubber stopper and an aluminium cap.

This medicine may be available in 4 pack sizes:

6 x 2 mL vials

5 x 2 mL vials

3 x 2 mL vials

1 x 2 mL vial

Australian Registration Number:  
AUST R 22435

### Who distributes Biological Therapies Methylcobalamin 10 mg in 2mL Injection?

#### Biological Therapies

A Division of Orthomolecular Medisearch  
Laboratories Pty Ltd  
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