

Biological Therapies

Methylcobalamin 10 mg in 2 mL Injection

Vitamin B 12 for Intramuscular Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Methylcobalamin 10 mg in 2 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 Methylcobalamin 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 Methylcobalamin Injection is used for

Methylcobalamin 10 mg in 2 mL Injection contains the active ingredient methylcobalamin (co-methylcobalamin) (Vitamin B12).

Methylcobalamin (co-methylcobalamin) belongs to a group of vitamins called cobalamins. The cobalamins are various different forms of Vitamin B12.

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.

Methylcobalamin Injection may be prescribed to help with the symptoms of pernicious anaemia, or for megaloblastic anaemia if Vitamin B12 deficiency is the diagnosed cause.

Peripheral and diabetic neuropathies:

Damage to the nervous system from disease may cause various new sensations or changes in strength or coordination. These changes are called neuropathies (diseases of the nerves), and if they affect the

extremities of the body, they are called peripheral. Peripheral neuropathies are a very common complication of diabetes mellitus.

Methylcobalamin Injection may help to treat peripheral neuropathies and may improve your symptoms.

Your doctor may have prescribed Methylcobalamin Injection for another reason.

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

Methylcobalamin Injection is not addictive.

Methylcobalamin Injection is only available from a medical practitioner.

Before you are given Methylcobalamin Injection

When you must not be given it:

Do not have Methylcobalamin 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 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.
- **you do not have a confirmed diagnosis that Vitamin B12 may be useful**
- **you are breastfeeding infants**
Vitamin B12 is distributed into breast milk. Therefore it is not recommended for breastfeeding mothers unless the expected benefits to the mother outweigh any potential risk to the infant.
- **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 Methylcobalamin Injection, talk to your doctor.

Before you have it injected:

Your doctor may test if you have an allergy to Methylcobalamin 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 Methylcobalamin 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

If you have not told your doctor about any of these conditions, tell them before you have Methylcobalamin 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.

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.

How Methylcobalamin Injection is given

Methylcobalamin Injection must only be given by a doctor or nurse.

Methylcobalamin Injection will be injected intramuscularly (into the buttock muscle) by your doctor.

How much is given:

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.

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 Methylcobalamin Injection.

Your doctor will tell you how long you should take Methylcobalamin 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 Methylcobalamin, so an overdose is not likely to occur.

But if you think that you or anyone else may have been given too much Methylcobalamin 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 Methylcobalamin Injection

Things you must do:

- **Tell all doctors, dentists and pharmacists who are treating you that you are being treated with Methylcobalamin Injection.**
- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with Methylcobalamin Injection.**
- **If you need to have any urine or blood tests tell your doctor that you are being given Methylcobalamin Injection. Methylcobalamin Injection may affect the results of some of these tests.**
- **Tell your doctor if you become pregnant while being treated**

with Methylcobalamin Injection.

- **Tell your doctor if you feel that giving Methylcobalamin 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 Methylcobalamin 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 Methylcobalamin Injection.

Methylcobalamin 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
- Any other mild allergies

These are usually mild side effects of using Methylcobalamin, but may be serious.

If any of the following happen, stop taking Methylcobalamin 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, breathing tubes, 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
- diarrhea
- heart failure
- vision problems
- loss of consciousness

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

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.

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 Methylcobalamin Injection

Store 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.**

Expiry date is 12 months from the date of manufacture. 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 or used for more than one person.

Product Description

What it 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.

6 x 2 mL vials

5 x 2 mL vials

3 x 2 mL vials

1 x 2 mL vial

Ingredients per vial:

Active Ingredient:

- mecobalamin (co-methylcobalamin) 10 mg

Other Ingredients

- sodium chloride
- water for injections

Supplier

Supplied and manufactured in Australia by:

Biological Therapies

A Division of Orthomolecular Medisearch Laboratories Pty Ltd.

Suite 5, 20-30 Malcolm Road
Braeside VIC 3195

Australian Registration Number:

AUST R 22435

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