Cobal-B12 injection

1 mg/1 mL

hydroxocobalamin (as acetate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Cobal-B12 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 or pharmacist has weighed the risks of you being given hydroxocobalamin against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Cobal-B12 injection is used for

Cobal-B12 injection is used for the prevention and treatment of anaemias associated with vitamin B12 deficiency. It is also used to treat diseases of nerves in the eyes.

Cobal-B12 injection is a form of vitamin B12.

Ask your doctor if you have any questions about why Cobal-B12 injection has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is not addictive.

Before you are given Cobal-B12 injection

When you must not be given it You must not be given Cobal-B12 injection if you have had an allergy to:

- any medicine containing hydroxocobalamin
- any of the ingredients listed at the end of this leaflet
- cobalt.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; skin rash, itching or hives.

You must not be given hydroxocobalamin to treat megaloblastic anaemia of pregnancy (this is a type of anaemia usually caused by the deficiency of another vitamin called folic acid).

You must not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged return it to your pharmacist for disposal.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

a disease of the spinal cord

 folate-deficient megaloblastic anaemia (a type of anaemia caused by the deficiency of another vitamin called folic acid).

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the possible risks and benefits involved.

If you have not told your doctor about any of the above, tell him/ her before you are given Cobal-B12 injection.

Taking other medicines

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

Some medicines and hydroxocobalamin may interfere with each other. These include:

- chloramphenicol, a medicine used to treat infections
- the contraceptive pill (birth control pill)
- · folic acid.

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

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while being treated with this medicine.

How Cobal-B12 injection is given

How much is given

Your doctor will decide what dose you will receive and how often you will receive it. This depends on your condition and other factors, such as your weight.

How it is given

Cobal-B12 injection is given as an injection, into a muscle. It must only be given by a nurse or doctor.

If you receive too much (overdose)

Cobal-B12 injection is given to you under the supervision of your doctor; it is very unlikely that you will receive too much.

However, if you experience severe side effects, immediately telephone your doctor or the Poisons Information Centre (phone 13 11 26 in Australia, or call 0800 764 766 in New Zealand) for advice, or go to Accident and Emergency at the nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Symptoms of an overdose may include the side effects listed in the 'Side effects' section, but are usually of a more severe nature.

Ask your doctor or pharmacist if you have any concerns.

While you are being given Cobal-B12 injection

Things you must do

If you are to be started on any new medicine, remind your doctor and pharmacist that you are being given Cobal-B12 injection.

Tell any other doctors, dentists, and pharmacists who treat you that you are being given this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given this medicine.

It may affect other medicines used during surgery.

If you become pregnant while you are being treated with this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are being given this medicine.

It may interfere with the results of some tests

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 any unwanted side effects.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being treated with Cobal-B12 injection.

This medicine helps most people with vitamin B12 deficiency, 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.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- diarrhoea
- nausea
- headache
- · vomiting
- dizziness
- acne
- skin rash
- · pain or redness at the injection site
- feeling hot or cold.

These side effects are usually mild.

If any of the following happen, tell your doctor immediately or go to the Accident and Emergency Department at your nearest hospital:

 signs of an allergic reaction, which may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin

- breathlessness, which may be very severe and usually worsens on lying down (due to a build-up of fluid in the lungs)
- changes in heart rate (fast, slow or irregular)
- · chest tightness or pain.

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

These side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After being given Cobal-B12 injection

Storage

Cobal-B12 injection is usually stored in the doctor's surgery or clinic, or at the pharmacy. The injection is kept in a cool dry place where the temperature stays below 25°C.

If you need to store Cobal-B12 injection, keep it in the original pack until it is time for it to be given.

If you take the ampoules out of the pack, they will not keep well.

Keep Cobal-B12 injection in a cool dry place, where the temperature stays below 25°C and protect from light.

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it in the car on hot days, or on window sills.

Heat and dampness can destroy some medicines.

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

Disposal

If your doctor tells you to stop using Cobal-B12 injection or it has passed its expiry date, ask your pharmacist what to do with any ampoules that are left over.

Product description

What it looks like

Cobal-B12 injection is a clear pale red liquid in a glass ampoule.

It is available in packs of 3 ampoules.

Ingredients

Active ingredient:

Cobal-B12 injection contains hydroxocobalamin acetate as the active ingredient.

Inactive ingredients:

- glacial acetic acid
- sodium chloride
- water for injections.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Amdipharm Mercury (Australia) Pty Ltd Level 9, 76 Berry Street North Sydney NSW 2060 Supplier: Juno Pharmaceuticals Pty Ltd Level 2, 6 Bond Street, South Yarra VIC 3141 AUST R: 285067

This leaflet was prepared on 24 April 2017.