

HYDROXO-B12 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.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using Hydroxo-B12 Injection?

Hydroxo-B12 contains the active ingredient Hydroxocobalamin chloride which is a form of vitamin B12. Hydroxo-B12 is used for the prevention and treatment of anemia's associated with vitamin B12 deficiency. It is also used to treat diseases of nerves in the eyes.

For more information, see Section [1. Why am I using Hydroxo-B12?](#) in the full CMI.

2. What should I know before I use Hydroxo-B12?

Do not use if you have ever had an allergic reaction to Hydroxo-B12 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.

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

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent any unwanted side effects.

For more information, see Section [2. What should I know before I use Hydroxo-B12 ?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Hydroxo-B12 and affect how it works. Tell your doctor or pharmacist if you are using any other medicines, including any that you buy without a prescription for your pharmacy, supermarket or health food shop.

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 Hydroxo-B12?

- Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight.
- Hydroxo-B12 Injection is given as an injection into a muscle. It must be only given by a nurse or doctor.

More instructions can be found in Section [4. How do I use Hydroxo-B12?](#) in the full CMI.

5. What should I know while using Hydroxo-B12?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or pharmacist that you visit that you are using Hydroxo-B12.• If you are going to have surgery, tell the surgeon or anesthetist that you are being given Hydroxo-B12 as it may affect other medicines used during surgery.
Looking after your medicine	<ul style="list-style-type: none">• Hydroxo-B12 Injection must be kept in a cool, dry place where the temperature stays below 25°C• If you need to store Hydroxo-B12 Injection, keep it in the original pack until it is time for it to be given.

For more information, see Section [5. What should I know while using Hydroxo-B12?](#) in the full CMI.

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 treated with Hydroxo-B12 Injection. This medicine helps most people with vitamin B12 deficiency, but it may have unwanted side effects in a few people. Tell your doctor or pharmacist if you notice any of the following and they are worrying you: diarrhoea, nausea, headache, vomiting, dizziness, acne, skin rash, pain or redness at the injection site. If any of the following happen, tell your doctor immediately or go to the Accident and Emergency Department at your nearest hospital: Signs of allergic reaction, which 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, changes to heart rate, chest tightness or pain.

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.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems. [Include if applicable]

WARNING: [Insert boxed warning, adapted for consumers, if applicable]

Hydroxo-B12 Injection

Active ingredient(s): [*Hydroxocobalamin chloride*] (*(hye-drox-oh-koe-BAL-a-min)*)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Hydroxo B-12. **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 [medicine name].**

Where to find information in this leaflet:

- [1. Why am I using Hydroxo-B12?](#)
- [2. What should I know before I use Hydroxo-B12?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Hydroxo-B12?](#)
- [5. What should I know while using Hydroxo-B12?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Hydroxo-B12

Hydroxo-B12 contains the active ingredient Hydroxocobalamin chloride which is a form of vitamin B12.

Hydroxo-B12 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.

2. What should I know before I use Hydroxo-B12?

Warnings

Do not use Hydroxo-B12 if:

- you are allergic to Hydroxocobalamin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Do not use Hydroxo-B12 if you have an allergy to cobalt

Check with your doctor if you:

- have any other medical conditions such as, a disease of the spinal cord, folate-deficiency megaloblastic anaemia (a type of anaemia caused by the deficiency of another vitamin called folic acid).

- take any medicines for any other condition

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.

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.

Medicines that may reduce the effect of Hydroxo-B12 include:

- Chloramphenicol, a medicine used to treat infections
- The contraceptive pill (birth control pill)
- Folic acid

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Hydroxo-B12.

4. How do I use Hydroxo-B12?

How much to take / use

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

If you use too much Hydroxo-B12

As Hydroxo-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,

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 Hydroxo-B12?

Things you should do

If you are to be started on any new medicine, remind your doctor and pharmacist that you are being given Hydroxo-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 the surgery.

Looking after your medicine

- Hydroxo-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.

Follow the instructions in the carton on how to take care of your medicine properly.

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

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.

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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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
<ul style="list-style-type: none"> • Diarrhoea • Nausea • Headache • Vomiting 	<p>Speak to your doctor or pharmacist if</p>

<ul style="list-style-type: none"> • Dizziness • Acne • Skin rash • Pain or redness at the injection site. This side effect is usually mild • Loss of pigmentation of the skin • Bowel motions may have a reddish colour • Urine may take on a pink or reddish tinge • Feeling tired, lacking energy • Sensation of feeling hot and cold 	<p>you have any of these less serious side effects and they worry you.</p>
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Serious side effects

Serious side effects	What to do
<p>Allergic Reactions</p> <ul style="list-style-type: none"> • Shortness of breath • Wheezing or difficulty breathing • Swelling of the face, lips, tongue or other parts of the body. • Skin rash • Itching or hives • Chest pain or chest discomfort 	<p>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.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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. 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 Hydroxo-B12 contains

Active ingredient (main ingredient)	Hydroxocobalamin as Hydroxocobalamin chloride
Other ingredients (inactive ingredients)	Sodium Chloride Water for Injections

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

What Hydroxo-B12 looks like

Hydroxo-B12 Injection is a clear dark red solution in a glass ampoule, it is available in packs of 3 ampoules.

Who distributes Hydroxo-B12

Aspen Pharmacare Australia Pty Limited
34-36 Chandos Street
St Leonards 2065
NSW Australia

Australian Registration Number:

AUST R 161606

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