Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about HYDROXO-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 this medicine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What HYDROXO-B12 Injection is used for

HYDROXO-B12 Injection contains hydroxocobalamin as the active ingredient which is a form of vitamin B12.

It 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.

Ask your doctor if you have any questions about why HYDROXO-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 it

When you must not be given it

You must not be given HYDROXO-B12 Injection if you have an allergy to:

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

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 it 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 are allergic to any other medicines or any foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, including:

- 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 breast-feeding.

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 them before you are given HYDROXO-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 may be affected by HYDROXO-B12 or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines. These include:

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

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

How it is given

How much is given

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

How it is given

HYDROXO-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)

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, tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital.

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 it

Things you must 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 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 HYDROXO-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.

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. This side effect is 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 else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

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

Do not be alarmed by this list of side effects.

You may not experience and of them.

After being given it

Storage

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.

If you need to store HYDROXO-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 may not keep as well.

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 HYDROXO-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

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

Ingredients

Active ingredient:

Each ampoule contains 1 mg/mL of hydroxocobalamin (as hydroxocobalamin chloride).

Inactive ingredients:

- sodium chloride
- · water for injections.

Sponsor

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Australian Registration number: AUST R 161606

This leaflet was prepared in October 2010.