

Consumer Medicine Information

VITA-B12 INJECTION

Hydroxocobalamin acetate (vitamin B12)

Solution for injection 1 mg/mL (as Hydroxocobalamin)

What is in this leaflet

Please read this leaflet carefully before you are given VITA-B12 INJECTION.

This leaflet answers some common questions about VITA-B12 INJECTION. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from www.medsafe.govt.nz.

Reading this leaflet 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 you using VITA-B12 INJECTION against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.

You may want to read it again.

What VITA-B12 INJECTION is used for

VITA-B12 INJECTION contains hydroxocobalamin acetate (vitamin B₁₂).

Vitamin B₁₂ is important for the function of several key body enzymes. It is needed for physical growth and development and for the formation of red blood cells in the bone marrow. This vitamin is also needed for the body to absorb folic acid and carbohydrates in the diet and for keeping the nervous system healthy.

Only small daily amounts of vitamin B₁₂ are required. Deficiency of vitamin B₁₂ may take months or years to develop, but eventually leads to anaemia, a condition in which the amount of oxygen-carrying pigment (haemoglobin) in the blood is reduced. Symptoms of vitamin B₁₂ deficiency anaemia include sore mouth and tongue, numbness and tingling in the arms and legs, memory loss and depression. The most common type of vitamin B₁₂ deficiency anaemia is Addisonian pernicious anaemia, in which absorption of vitamin B₁₂ from the stomach does not take place properly.

VITA-B12 INJECTION is used to replace the body's low vitamin B₁₂ levels caused by:

- Addisonian pernicious anaemia



- other vitamin B deficiency anaemias
- stomach surgery
- strict vegetarianism.

VITA-B12 INJECTION is also used to treat tobacco amblyopia (smoker's blindness) and another eye condition called Leber's optic atrophy.

Your doctor may have prescribed this medicine for another reason.

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

VITA-B12 INJECTION is not addictive.

Before you are given VITA-B12 INJECTION

VITA-B12 INJECTION is not suitable for everyone.

When you must not be given it

Do not use VITA-B12 INJECTION if you are allergic to any medicine containing hydroxocobalamin, cobalt or any of the ingredients listed at the end of this leaflet.

Do not use it if you have a condition called megaloblastic anaemia and are pregnant.

Do not use it after the expiry date printed on the pack.

If you are being given this medicine after the expiry date has passed, it may not work as well.

Do not use it if the packaging is torn or shows signs of tampering, or if the solution in the ampoule is discoloured or cloudy.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you are given it

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:

- 1. have allergies to any other medicines, foods, preservatives or dyes.**
- 2. are pregnant or plan to become pregnant.**
Your doctor will discuss with you the possible risks and benefits involved.
- 3. are breast-feeding or plan to breast-feed.**
The active ingredient in VITA-B12 INJECTION passes into breast milk. Your doctor



will discuss the risks and benefits of using hydroxocobalamin if you are breast-feeding.

If you have not told your doctor or pharmacist about any of the above, tell them before being given VITA-B12 INJECTION.

Taking other medicines

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

Tell any health professional who is prescribing a new medicine for you that you are using VITA-B12 INJECTION.

Some medicines and VITA-B12 INJECTION may interfere with each other. These include:

- chloramphenicol
- antibiotics (antibacterials) for any type of infection
- antimetabolites (medicines used to treat cancer)
- the contraceptive pill (birth control pill)
- folic acid.

The above medicines may be affected by VITA-B12 INJECTION, or may affect how well it works. You may need different amounts of VITA-B12 INJECTION or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using VITA-B12 INJECTION.

How VITA-B12 INJECTION is given

How it is given

VITA-B12 INJECTION is given as an injection into a muscle by a doctor or nurse.


Do not leave your doctor's surgery after a VITA-B12 INJECTION injection until your doctor tells you to.

Very occasionally, VITA-B12 INJECTION can cause a sudden severe allergic reaction (anaphylaxis) soon after the injection.

How much you will be given

Your doctor will decide how many injections you need, and how often you should receive them.

For Addisonian pernicious anaemia and most other types of vitamin B₁₂ deficiency anaemia, provided your nervous system is not affected, the usual dose is 250 micrograms to 1000 micrograms every second day for up to two weeks, then 250 micrograms once a week until your vitamin B₁₂ levels are normal. A 1000 microgram injection is often given every two to three months to keep your vitamin B₁₂ levels in the



normal range. If your nervous system has been affected, the starting dose is 1000 micrograms every second day, then 1000 micrograms every two months, provided your condition is improving.

For vitamin B₁₂ deficiency anaemia caused by stomach surgery, stomach disorders in which vitamin B₁₂ is not absorbed normally and strict vegetarianism, the usual dose is 1000 micrograms every two to three months.

If you have smoker's blindness or Leber's optic atrophy, the usual starting dose is at least 1000 micrograms given every day for two weeks, then twice weekly, provided you are responding well. Your doctor may then give you a 1000 microgram injection once a month.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

This depends on your condition and whether or not you are taking any other medicines.

If you receive the wrong dose, VITA-B12 INJECTION may not work as well and your problem may not improve.

How long you will be given it

Depending on the disorder you are being given VITA-B12 INJECTION for, you may need regular injections long-term.

While you are using VITA-B12 INJECTION

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using VITA-B12 INJECTION. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are being given this medicine.

If you become pregnant while using this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do regular blood tests to make sure VITA-B12 INJECTION is working effectively for you.

See your doctor if you feel that your condition is not improving or getting worse.

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.

This medicine is only intended for the use of the patient it has been prescribed for.

Do not use VITA-B12 INJECTION to treat any other complaints unless your doctor tells you to.

Things to be careful of



Be careful driving or operating machinery until you know how VITA-B12 INJECTION affects you.

In case of overdose

If you are given too much

Immediately telephone your doctor, or the Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have been given too much VITA-B12 INJECTION.

Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using VITA-B12 INJECTION.

Like all medicines, VITA-B12 INJECTION may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention 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
- red colour faeces
- pink or reddish tinge urine
- nausea
- headache
- vomiting
- dizziness
- acne
- skin rash
- pain or redness at the injection site
- generalised itching
- reddening of skin
- loss of pigmentation of skin and mucosa
- feeling hot or cold.

These side effects are usually mild.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:



- serious allergic (hypersensitivity) reaction. Symptoms include swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, severe skin rash, itching or hives, nausea, dizziness, fever, chills, hot flushes, feeling faint or dizzy (low blood pressure)
- 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.

These are very serious side effects; you may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any unusual acne-like eruptions on your skin.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not mentioned in this leaflet.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using VITA-B12 INJECTION

Storage

If you are keeping a supply of VITA-B12 INJECTION at home:

Keep VITA-B12 INJECTION in a cool dry place where the temperature stays below 25°C. Protect from light.

Do not store it or any other medicine in the bathroom, near a sink, or on a window sill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it and any other medicine 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.

Do not keep VITA-B12 INJECTION past its expiry date.

Disposal

Return any unused medicine, and any medicine past its expiry date (as shown on the dispensing label or on the packaging) to your pharmacy.

Product description

What it looks like



VITA-B12 INJECTION is a clear, red solution supplied in single dose ampoules. It is available in packs of 3 ampoules.

Ingredients

Active ingredient:

- hydroxocobalamin acetate

Inactive ingredients:

- sodium chloride
- glacial acetic acid
- water for injections

Sponsor details

BNM Group
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Browns Bay
Auckland 0753

Ph: 0800 565 633

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