

Hydroxocobalamin 1mg in 1ml Solution for injection

This leaflet contains important information about Hydroxocobalamin Injection.

Read all of this leaflet carefully before you start your treatment with this medicine.

1. Keep this leaflet. You may need to read it again.
2. If you have further questions, please ask your doctor.
3. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

In this leaflet

1. What is Hydroxocobalamin Injection and what is it for
2. Before you are given Hydroxocobalamin Injection
3. How Hydroxocobalamin Injection is used
4. Possible side effects
5. How Hydroxocobalamin Injection is stored
6. Further information

1. What is Hydroxocobalamin Injection and what is it for

This medicine contains Hydroxocobalamin which is a form of Vitamin B₁₂. It is given for:

- Addisonian pernicious anaemia (caused when absorption of Vitamin B₁₂ from the stomach is reduced).
- Tobacco amblyopia (poor sight caused by toxins such as tobacco).
- Leber's atrophy (degeneration of the optic nerve resulting in loss of central vision).
- Treatment/prevention of other macrocytic anaemias due to deficiency in vitamin B₁₂.

Vitamin B₁₂ is needed for physical growth and development and for the formation of red blood cells in the bone marrow. It is also required for absorption of folic acid and carbohydrates from food and for keeping the nerve (neurological) system healthy.

The body only requires a small amount of the vitamin daily so a deficiency may take months or even years to develop. Eventually, the formation of abnormally large red blood cells (macrocytes) with reduced ability to carry oxygen from enlarged cells (megaloblasts) in the bone marrow, gives rise to anaemia. Symptoms of Vitamin B₁₂ deficiency anaemia include sore mouth and tongue, numbness and tingling in the arms and legs, memory loss and depression.

2. Before you are given Hydroxocobalamin Injection

Hydroxocobalamin Injection should not be used if you:

- Are allergic (hypersensitive) to any ingredient in the preparation (see section 6 Further Information).

When you are receiving Hydroxocobalamin injections:

- If you are aware of abnormal heart beats, tell your doctor or nurse.
- If, after several weeks' treatment, you do not feel any improvement, discuss this with your doctor or nurse.

Taking other medicines

Tell your doctor if you are taking or have recently taken any medicines including medicines obtained without a prescription. Hydroxocobalamin can interfere with the action of some other drugs and some drugs can have an effect on Hydroxocobalamin. The following drugs can cause some problems when taken together with Hydroxocobalamin Injection:

- chloramphenicol (an antibiotic) can reduce the effects of Hydroxocobalamin.
- oral contraceptives may reduce the blood levels of Hydroxocobalamin.

The following medicines **do not** alter the effectiveness of Hydroxocobalamin Injection but make it more difficult to measure the amount of Vitamin B₁₂ in the body:

- antibiotics.
- antimetabolites (used to treat tumours and blood disorders).

Pregnancy and breast-feeding

- Hydroxocobalamin injection should not be used for the treatment of megaloblastic anaemia of pregnancy. Tell your doctor if you are pregnant, think you might be pregnant or are trying to become pregnant.
- If you are breast feeding you should tell your doctor before you are given this medicine. Hydroxocobalamin passes into the breast milk but is unlikely affect your baby.

Driving and using machines

- Your medicine is unlikely to affect your ability to drive or to operate machinery. However, some people may feel dizzy or drowsy when given Hydroxocobalamin injection. If this happens to you, do not drive or operate machinery.

3. How Hydroxocobalamin Injection is used

Hydroxocobalamin will be given to you by injection into a muscle. The dose depends on your individual needs and responses to treatment. Your blood levels of Vitamin B₁₂ and folic acid are likely to be monitored both before and during treatment. If you have doubts about the treatment or want more information about your medicine or the monitoring procedure, do ask the doctor or nurse.

Adults and Children

Initial dose: This varies between **250 mcg** and **1mg** given daily or on alternative days. The actual dosage depends on your specific illness and your response to treatment.

Maintenance dose: Your doctor will check your condition regularly. When he/she feels that your health has improved sufficiently, your dose of Hydroxocobalamin Injection will be reduced to **1mg** every 2-3 months or as required.

If more Hydroxocobalamin is used than should be:

Being given more than the intended dose of hydroxocobalamin is unlikely to cause a problem requiring treatment. Tell the doctor if you are experiencing any side effects or think you may be reacting badly so that he/she can give appropriate treatment.

If you have already left the medical premises, contact your nearest hospital, doctor or nurse.

If you miss a dose of Hydroxocobalamin:

It is unlikely that you will miss a dose as your doctor or nurse will be giving it to you. However, it is important not to have a double dose if you have missed one. Ask your doctor or nurse when you should have the next dose.

If you have any further questions on the use of this product, ask your doctor or nurse.

4. Possible side effects

Like all medicines, Hydroxocobalamin Injection can cause side effects although not everyone gets them.

Tell your doctor immediately if you experience any of the following symptoms after you have been given the injection. Although they are very rare, these symptoms can be serious.

- swelling of the lips and face, difficulty in breathing, skin rash and redness (these may be symptoms of a serious allergic reaction)
- irregular heartbeat (caused by low levels of potassium in the blood) during early stages of treatment.

Other side effects

Itching, rash; fever, feeling unwell, chills, hot flushes; feeling or being sick (nausea or vomiting), diarrhoea, unusual coloured urine; headache, dizziness, tremble or shakes, feeling of pins and needles; acne-like and blistering skin eruptions; pain including pain at the injection site.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (Website: www.mhra.gov.uk/yellowcard). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How Hydroxocobalamin Injection is stored

- Keep out of the reach and sight of children
- Do not use Hydroxocobalamin Injection after the expiry date which is stated on the ampoule and carton after Exp.: The expiry date refers to the last day of that month.
- Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

Hydroxocobalamin Injection is a sterile solution for injection containing hydroxocobalamin acetate. It also contains water and sodium chloride and may also contain a very small amount of acetic acid and/or sodium hydroxide.

The product is available in 1ml ampoules in packs of 5 ampoules.

The Marketing Authorisation for Hydroxocobalamin Injection is held by Auden Mckenzie (Pharma Division) Ltd., Whiddon Valley, Barnstaple, North Devon, EX32 8NS, UK. Telephone: +44(0)1271 385257.

Hydroxocobalamin Injection is manufactured by Rotexmedica GmbH Arzneimittelwerk Busenstrasse 4, Trittau, Schleswig-Holstein, 22946, Germany.

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