Hydroxocobalamin 1mg/ml Solution for Injection PIL - UK

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 amyotrophy (poor sight caused by toxins such as tobacco).
- Leber’s atrophy (degeneration of the optic nerve resulting in loss of visual 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 the lungs to the tissues. 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 injection:
- 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.
- antimitobolites (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 to 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 250mcg 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 hydrocobalamin 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.

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Item no: BBA1142

Originator: D Rhodes

Dimensions: 148 x 297

Min Body Text Size: 8pt

Supplier: Rotexmedica GmbH

Colours

1. Black

Non Printing Colours

1. 2. 3. 4. 5. 6.

* Please note that only Artwork Studio is permitted to make changes to the above artwork. No changes are permitted by any 3rd party other than added notes and mark ups for required changes.
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 blistery 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 sight and reach of children
• Do not store above 25°C
• Keep container in the outer carton
• 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 Accord Healthcare Limited

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