

## PACKAGE LEAFLET: INFORMATION FOR THE USER

# Hydroxocobalamin 1mg in 1ml Solution for injection

**Read all of this leaflet carefully before you start this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What Hydroxocobalamin Injection is and what it is used for
2. What you need to know before you are given Hydroxocobalamin Injection
3. How Hydroxocobalamin Injection is given
4. Possible side effects
5. How Hydroxocobalamin Injection is stored
6. Contents of the pack and other information

## 1. What Hydroxocobalamin Injection is and what it is used for

This medicine contains Hydroxocobalamin which is a form of Vitamin B<sub>12</sub>. It is given for:

- Addisonian pernicious anaemia (caused when absorption of Vitamin B<sub>12</sub> 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 B<sub>12</sub>.

Vitamin B<sub>12</sub> 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 B<sub>12</sub> deficiency anaemia include sore mouth and tongue, numbness and tingling in the arms and legs, memory loss and depression.

This injection is usually given to you by your doctor or someone else trained to give it to you.

## 2. What you need to know before you are given Hydroxocobalamin Injection

### Do not use Hydroxocobalamin Injection:

- if you are allergic to hydroxocobalamin or any of the other ingredients of this medicine (listed in section 6).

### Warnings and precautions

Talk to your doctor or nurse before using 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.

## Other medicines and Hydroxocobalamin Injections

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. 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 B<sub>12</sub> in the body:

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

## Pregnancy and breast-feeding

### Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Hydroxocobalamin injection should not be used for the treatment of megaloblastic anaemia of pregnancy unless vitamin B<sub>12</sub> deficiency has been demonstrated.

### Breast-feeding

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.

**This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium-free'.**

## 3. How Hydroxocobalamin Injection is given

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 B<sub>12</sub> 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, 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. For initial treatment of tobacco amblyopia and Leber's atrophy, your doctor may decide to use doses higher than 1mg.

**Maintenance dose:** Your doctor will check your condition regularly. When they feel 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 your doctor if you are experiencing any side effects or think you may be reacting badly so that they 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, this medicine 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

**Not known** (frequency cannot be estimated from the available data)

- Acniform and bullous eruptions (acne-like and blistering skin eruptions).
- Headache, dizziness
- Nausea (feeling sick), vomiting, diarrhoea
- Malaise (feeling unwell)
- Rash, itching
- Injection site reactions including injection site pain, injection site erythema, injection site pruritus, injection site induration, and injection site swelling
- Exanthema (a widespread skin rash)
- Chromaturia (unusual coloured urine)
- Fever
- Hot flushes (a feeling of intense heat with sweating and rapid heartbeat)
- Chills (feeling of coldness accompanied by shivering)
- Paraesthesia (feeling of pins and needles)
- Tremor (tremble or shakes)
- Hypokalaemia (decreased potassium levels in the blood)
- Reactive thrombocytosis (body produces too many platelets).

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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

### 5. How Hydroxocobalamin Injection is stored

- Keep this medicine 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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6. Contents of the pack and other 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.

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