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

This medicine contains Hydroxocobalamin which is a form of Vitamin B12. It is given for:
- Addissonian pernicious anaemia (caused when absorption of Vitamin B12 from the stomach is reduced).
- Tobacco amytoplexia (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 (megalocytes) with reduced ability to carry oxygen from enlarged cells (megaloblasts) in the bone marrow, gives rise to anaemia. Symptoms of iron deficiencies may take time to develop. The following medicines can cause some problems when taken together with Hydroxocobalamin Injection:
- Chloramphenicol (an antibiotic) can reduce the effects of Hydroxocobalamin.

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.

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 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, ask the 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 medicines can cause some problems when taken together with Hydroxocobalamin Injection:
- Chloramphenicol (an antibiotic) can reduce the effects of Hydroxocobalamin.

Pregnancy, breast-feeding and fertility

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.

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.
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 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, 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 blistery skin eruptions).
- Headache, dizziness
- Nausea (feeling sick), vomiting, diarrhoea
- Malaise (feeling unwell)
- Rash, itching
- Injection site reactions including injection site induration, and injection site erythema, injection site pain, injection site swelling (Reactions at the site of the injection)
- 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 (trembles 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.

5. How Hydroxocobalamin Injection is stored

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.

Marketing Authorisation Holder
Accord Healthcare Limited
Sage House
319 Pinner Road
North Harrow
Middlesex
HA1 4HF
United Kingdom

Manufacturers
Parnpharma GmbH
Bursenstrasse 4, Trittau, Schleswig-Holstein, 22946, Germany.

This leaflet was updated in January 2020

Hydroxocobalamin 1mg/ml Solution for Injection PIL - UK

Item number: BBBA7147

Originator: 5Aron
Origination Date: 191219
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Report for 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 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.

6. Contents of the pack and other information

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