

Package leaflet: Information for the patient

Hydroxocobalamin 1 mg/ml Solution for Injection Hydroxocobalamin (as hydroxocobalamin acetate)

Read all of this leaflet carefully before you start taking 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 any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is Hydroxocobalamin 1mg/ml Solution for Injection. It will be referred to as Hydroxocobalamin Injection for ease of use hereafter.

What is in this leaflet:

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

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

Hydroxocobalamin injection is an injection which contains hydroxocobalamin acetate. It is used to treat deficiency of vitamin B12 which causes various types of anaemia (reduction in the number of red blood cells). Most people get enough vitamin B12 from their food, but if you have had stomach surgery, or certain diseases of the intestines, or a restricted diet, you may not absorb enough vitamin B12. It is used to treat conditions called tobacco amblyopia and Leber's optic atrophy, which result in dimming of vision.

2. What you need to know before you use Hydroxocobalamin Injection

Do not use Hydroxocobalamin Injection

- If you know you are allergic to hydroxocobalamin injection or any of the other ingredients present in this medicine (see section 6 of this leaflet)

Warnings and precautions

Talk to your doctor before using Hydroxocobalamin Injection:

- If you have suffered from any heart problems.
- If you have megaloblastic anaemia. This is a blood disorder where you have larger than normal blood cells.
- If you have a known cobalt allergy. Hydroxocobalamin contains cobalt.

Your doctor may want to monitor your response to this medicine carefully, particularly if you are young or elderly. This will probably involve regular examination of your blood.

Other medicines and Hydroxocobalamin Injection

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

Some medicines can interact with Hydroxocobalamin injection which can significantly alter their effects. These drugs include:

- Chloramphenicol (an antibiotic used to treat infections)
- Oral contraceptives

Antibiotics (used to treat infections) and antimetabolites (used to treat some cancers) can affect blood tests used to measure vitamin B12.

Pregnancy and breast-feeding

Hydroxocobalamin injection should not be used in pregnancy for treating a kind of anaemia called megaloblastic anaemia of pregnancy, unless you also have a Vitamin B12 deficiency. Hydroxocobalamin injection is found in breast milk but it is unlikely that it will harm your baby.

Tell your doctor **before** you are given this medicine if you are pregnant, think you may be pregnant or are planning to become pregnant or are breast-feeding.

Hydroxocobalamin injection should not be used to treat certain types of anaemia caused by pregnancy.

Driving and using machines

Hydroxocobalamin injection should not affect your ability to drive or use machinery.

Hydroxocobalamin Injection contains Sodium

This injection contains less than 1mmol (23mg) of sodium per 1ml (essentially ‘sodium-free’)

3. How to use Hydroxocobalamin Injection

Hydroxocobalamin injection is administered by injection into a muscle.

Your doctor will decide the correct dose for you depending on your circumstances. You will be given a starting treatment and then maintenance.

The injection may need to be repeated depending on your response. Hydroxocobalamin injection is also suitable for use in children and the elderly.

What to do if you have been given more Hydroxocobalamin injection than you should

This is unlikely because the dose will be administered by a health professional. If you suspect you have been given too much, you should tell your doctor immediately.

Medical check-ups

While you are receiving this medicine, your doctor will want you to have regular blood tests.

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

4. Possible sideeffects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately. These reactions might also occur on handling the injection directly.

- Allergic reactions to the active ingredient, hydroxocobalamin is rare but may cause unpleasant sensation that causes the desire to or reflex to scratch (itching), widespread rash (exanthema) and exceptionally as an anaphylactic reaction (swelling and shortness of breath)
- Acne like and blister eruptions have been reported rarely

- You may get an irregular heart beat during the early stages of treatment.
- Thrombocytosis (where you have a high number of platelets in your blood)
- You may get a headache or feel feverish, cold, dizzy, sick or unwell
- You may develop a wide spread rash
- You may feel some itching or pain at the site of the injection
- Your skin may become hard at the site of injection
- Your skin might die around the site of injection
- You may develop a feeling of ‘pins and needles’ or tremor
- During initial treatment your potassium levels may drop, this may cause you to get muscle weakness.
- You may develop pink or red coloured urine.

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 as follows:

UK: 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

Ireland: via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax +353 1 6762517. Website: www.hpra.ie; Email: medsafety@hpra.ie.

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

5. How to store Hydroxocobalamin injection

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and ampoule label after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C

Do not freeze.

Store in the original package.

Single use only, discard any unused content.

6. Contents of the pack and other information

What Hydroxocobalamin Injection contains

The active substance is hydroxocobalamin. Each ampoule contains 1 mg/ml hydroxocobalamin (as hydroxocobalamin acetate). 1 mg/ml of hydroxocobalamin equals 1,000 micrograms/ml.

The other ingredients are:

Sodium chloride, glacial acetic acid, sodium acetate trihydrate and water for injection.

What Hydroxocobalamin injection looks like and contents of the pack

Hydroxocobalamin injection is a red, clear sterile solution for injection.

Each glass ampoule contains 1ml of solution for injection. One ml of solution for injection contains 1.096 mg hydroxocobalamin acetate equivalent to 1 mg hydroxocobalamin (vitamin

B₁₂). Each carton contains five x 1ml ampoules.

Marketing Authorisation Holder and Manufacturer

G.L. Pharma GmbH,
Schlossplatz 1, 8502 Lannach, Austria

This medicinal product is authorised in the following Member States of the EEA under the following names:

Ireland: Hydroxocobalamin 1mg/ml Solution for Injection

UK: Hydroxocobalamin 1mg/ml Solution for Injection

This leaflet was last revised in 05/2024.