

Package leaflet: Information for the patient
Hydroxocobalamin G.L. Pharma 1 mg/ml solution for injection
hydroxocobalamin

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Hydroxocobalamin G.L. Pharma is and what it is used for

Hydroxocobalamin G.L. Pharma contains the active substance hydroxocobalamin (vitamin B₁₂). Hydroxocobalamin G.L. Pharma is used for prevention and treatment of pernicious anaemia (anemia due to vitamin B₁₂ deficiency) and other types of vitamin B₁₂ deficiency when tablets are not considered sufficient or appropriate.

2. What you need to know before you use Hydroxocobalamin G.L. Pharma

Do not use Hydroxocobalamin G.L. Pharma

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

Other medicines and Hydroxocobalamin G.L. Pharma

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important if you are taking:

- birth control pills. Birth control pills may decrease the blood levels of vitamin B₁₂.
- medicines for infection (common antibiotics, chloramphenicol)

Pregnancy and breast-feeding

Hydroxocobalamin G.L. Pharma can be used during pregnancy and breast-feeding.

There are no known negative effects on the foetus when using this medicine during pregnancy. Vitamin B₁₂ is excreted into breast milk but is not likely to have any effects on the child at recommended doses.

Driving and using machines

Hydroxocobalamin G.L. Pharma has no or negligible influence on the ability to drive and use machines.

Hydroxocobalamin G.L. Pharma contains sodium

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

3. How to use Hydroxocobalamin G.L. Pharma

Your doctor will tell you what your dose will be and how often you will receive it. Ask your doctor or nurse if you are in doubt. Only your doctor may change the dose.

You will receive the injection from a doctor or a nurse. Hydroxocobalamin G.L. Pharma will be given into a muscle or under the skin.

The recommended dose is:

- Initial dose: 1 ampoule daily or every other day, continued for 1 to 2 weeks or until improvement occurs
- Maintenance therapy: 1 ampoule every 1 to 3 months

The duration of treatment depends on the particular cause of your disease and up to lifelong treatment may be necessary.

If you use more Hydroxocobalamin G.L. Pharma than you should

An overdose is unlikely because the dose will be administered by a health professional. If you think you have received too much Hydroxocobalamin G.L. Pharma contact your doctor or nurse. Normally there are no symptoms of overdose.

If you forget to use Hydroxocobalamin G.L. Pharma

Contact your doctor or nurse if you think a dose has been missed.

If you stop using Hydroxocobalamin G.L. Pharma

Contact your doctor if you want to stop treatment.

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

4. Possible side effects

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

Serious side effects

Tell your doctor immediately if you experience any of the following symptoms after you have been given the injection. These symptoms can be serious.

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

- Swelling of the lips, face or throat, difficulty in swallowing and breathing, skin rash, itching and redness (these may be symptoms of a serious allergic reaction and angioedema)
- Irregular heartbeat (caused by low levels of potassium in the blood)

Other side effects

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

- Acne rash or blisters
- Skin redness, urticaria (hives), rash, itching
- Dizziness, headache, feeling unwell, fever, chills, hot flushing
- Uncontrolled trembling or shaking movements in one or more parts of your body
- Paresthesia, commonly known as 'pins and needles', where part of the body (typically a foot or hand)

- begins to tingle and becomes numb, or 'falls asleep'
- Diarrhoea, nausea, vomiting
- Abnormal coloration of the urine
- Decrease in kidney functions due to calcium deposits (oxalate nephropathy)
- Reactions at the injection site, such as pain, swelling, hardening or damage of the tissue

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 national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hydroxocobalamin G.L. Pharma

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 after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not freeze.

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

What Hydroxocobalamin G.L. Pharma contains

- The active substance is: hydroxocobalamin (vitamin B₁₂). One 1 ml ampoule contains 1.04 mg hydroxocobalamin acetate equivalent to 1 mg hydroxocobalamin (vitamin B₁₂).
- The other ingredients are: sodium acetate trihydrate (for pH adjustment), acetic acid glacial (for pH adjustment), sodium chloride, water for injection.

What Hydroxocobalamin G.L. Pharma looks like and contents of the pack

Hydroxocobalamin G.L. Pharma 1 mg/ml solution for injection is a clear, red solution.

The product is available in packs of 3 and 5 clear glass ampoules marked with two coloured rings. Each ampoule contains 1 ml of solution.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

Sweden: Hydroxocobalamin G.L. Pharma

Norway: Hydroxocobalamin G.L. Pharma

Finland: Hydroxocobalamin G.L. Pharma

Iceland: Hydroxocobalamin G.L. Pharma

This leaflet was last revised in 2023-06-29

The following information is intended for healthcare professionals only:

How the Hydroxocobalamin G.L. Pharma ampoule is opened

1. Localise the OPC (one-point-cut), which is marked on the top section of the ampoule with a coloured dot, and let it point upward.
2. Make sure to remove all the liquid from the top of the ampoule by gently tapping it.
3. Put the other hand on the top of the ampoule with your thumb on the point.
4. Break the neck of the ampoule in the direction away from you.

The usual dose is:

Severe acute cases of diagnosed or suspected neuropathy: 1 ampoule administered intramuscularly or subcutaneously daily or every other day for 1 - 2 weeks until blood values are normalised.

Severe acute cases without neuropathy: 1 ampoule is given every other day, for up to 5 times in total.

Maintenance dose: 1 ampoule intramuscularly or subcutaneously every month to every third month.