

PACKAGE LEAFLET: INFORMATION FOR THE USER

COBALIN-H® 1000 microgram/ml INJECTION

(hydroxocobalamin)

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 any 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.

The name of your medicine is Cobalín-H 1000 microgram/ml Injection, it will be referred to as Cobalín-H Injection throughout the PIL for ease hereafter.

What is in this leaflet:

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

1. WHAT COBALIN-H INJECTION IS AND WHAT IT IS USED 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 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 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 enlarged cells (megaloblasts) in the bone marrow, gives rise to anaemia. Symptoms of Vitamin B₁₂ 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 COBALIN-H INJECTION IS GIVEN

Do not use Cobalín-H Injection:

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

Warnings and Precautions:

Talk to your doctor or nurse before using Cobalín-H 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.

Other medicines and Cobalín-H Injection

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

Cobalín-H Injection can interfere with the action of some other drugs and some drugs can have an effect on Cobalín-H Injection. The following drugs can cause some problems when taken together with Cobalín-H Injection:

- chloramphenicol (an antibiotic) can reduce the effects of Cobalín-H Injection.
- oral contraceptives may reduce the blood levels of Cobalín-H Injection.

The following medicines do not alter the effectiveness of Cobalín-H Injection but make it more difficult to measure the amount of Vitamin B₁₂ in the body:

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

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. Cobalín-H 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. Cobalín-H Injection passes into the breast milk but is unlikely affect your baby.

Fertility

No data available

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 Cobalín-H Injection. If this happens to you, do not drive or operate machinery.

Cobalín-H Injection contains sodium

Cobalín-H Injection contains less than 1mmol sodium (23 mg) per 1ml (essentially "sodium-free").

3. HOW COBALIN-H INJECTION IS GIVEN

Cobalín-H Injection 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.

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and Children

Initial dose: This varies between 250 microgram and 1000 microgram 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 Cobalin-H Injection will be reduced to 1mg every 2-3 months or as required.

If you use more Cobalin-H Injection than you should :

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 forget to take Cobalin-H injection:

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 medicine, ask your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

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

Rare: may affect up to 1 in 1,000 people

- Acniform and bullous eruptions (acne-like and blistering skin eruptions).

Not known: frequency cannot be estimated from the available data

- 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 (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 (tremble or shakes)
- Hypokalaemia (decreased potassium levels in the blood)
- Reactive thrombocytosis (body produces too many platelets).

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 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 TO STORE COBALIN-H INJECTION

Keep this medicine out of the sight and reach of children. Store below 25°C and protect from light.

The product should not be used if it is not a clear red liquid or if it contains visible particles.

Do not use Cobalin-H 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

What Cobalin-H Injection contains

The **active substance** is: hydroxocobalamin 1000 microgram/ml.

The **other ingredients** are: sodium dihydrogen orthophosphate, sodium chloride and Water for Injections with sodium hydroxide and/or hydrochloric acid as pH adjusters.

The product is suitable for vegetarians and vegans.

What Cobalin-H Injection looks like and contents of the pack

The product is a clear red liquid, supplied in 5 clear glass vials. Each vial contains 1000 micrograms hydroxocobalamin.

Marketing Authorisation Holder

Amdipharm UK Limited, Capital House, 85 King William Street, London EC4N 7BL, UK (send all enquiries to this address).

Manufacturer

Amdipharm UK Limited, Capital House, 85 King William Street, London EC4N 7BL, UK

*Cobalin-H injection is a registered trade mark

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