Package leaflet: Information for the user

Hydroxocobalamin 1000 micrograms/ml solution for injection

hydroxocobalamin

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

What is in this leaflet

1. What Hydroxocobalamin 1000 micrograms/ml solution for injection is and what it is used for
2. What you need to know before you are given Hydroxocobalamin 1000 micrograms/ml solution for injection
3. How you will be given Hydroxocobalamin 1000 micrograms/ml solution for injection
4. Possible side effects
5. How to store Hydroxocobalamin 1000 micrograms/ml solution for injection
6. Contents of the pack and other information

1. What Hydroxocobalamin 1000 micrograms/ml solution for injection is and what it is used for

Hydroxocobalamin 1000 micrograms/ml solution for injection contains hydroxocobalamin, a form of Vitamin B12, which is an essential vitamin which is needed for production of red blood cells.

Vitamin B12 contains cobalt.

It is used to prevent and treat certain types of anaemia, including Addisonian pernicious anaemia, and other kinds of anaemia which result from a deficiency of Vitamin B12.

It is also used to treat conditions called tobacco amblyopia and Leber's optic atrophy, which result in a dimming of vision.

In this leaflet, Hydroxocobalamin 1000 micrograms/ml solution for injection will be called Hydroxocobalamin solution for injection.

2. What you need to know before you are given Hydroxocobalamin 1000 micrograms/ml solution for injection

You should not be given Hydroxocobalamin solution for injection
- if you are allergic to hydroxocobalamin or any of the other ingredients of this medicine (listed in section 6).

If the above applies to you talk to your doctor, pharmacist or nurse.

Warnings and precautions
Check with your doctor before being given Hydroxocobalamin solution for injection if:
- you are pregnant or are planning to become pregnant;
- you are breast-feeding.

Talk to your doctor or nurse if you have a known cobalt allergy.

Other medicines and Hydroxocobalamin solution for injection
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking any of the following medicines:
- Antibiotics (for treating infections) or antimetabolites (medicines which stop cells dividing, such as mercaptopurine for leukaemia), as these treatments may interfere with tests to measure the levels of Vitamin B12 in your blood or urine;
- An antibiotic called chloramphenicol, as you may not respond well to Hydroxocobalamin solution for injection;
- The contraceptive 'pill';
- Any other medicine, including medicines obtained without a prescription.

Pregnancy and breast-feeding
Hydroxocobalamin solution for injection should not be used for the treatment of megaloblastic anaemia of pregnancy, unless you have a vitamin B12 deficiency.
Hydroxocobalamin solution for injection is found in breast-milk, but it is unlikely that it will harm your baby.
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 being given this medicine.

Driving and using machines
Hydroxocobalamin solution for injection may cause dizziness. If this happens to you, do not drive or use machinery .

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

3. How you will be given Hydroxocobalamin solution for injection

Hydroxocobalamin solution for injection will be given to you by your doctor or nurse.

Important:
Your doctor will choose the dose that is right for you.

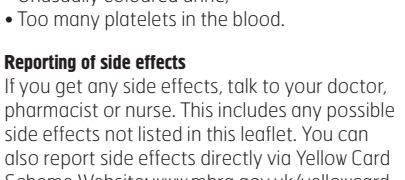
You will be given Hydroxocobalamin solution for injection by your doctor or nurse as an injection into a muscle. Your doctor will choose the dose that is right for you. You may be given it just once or it may be repeated every other day, weekly or monthly, depending on how much your body needs.

Adults and Children
- Treatment of anaemia:
  - Without neurological (nervous system) involvement:
    Initially 250 – 1000 micrograms, every other day for 1 to 2 weeks, then 250 micrograms weekly until the blood tests are normal.
    Maintenance dose: 1000 micrograms (1 ampoule) every 2 to 3 months.
  - With neurological involvement:
    1000 micrograms (1 ampoule) every other day for as long as improvement is noticed.
    Maintenance dose: 1000 micrograms (1 ampoule) every 2 months.

- Prevention of anaemia:
  1000 micrograms (1 ampoule) every 2 to 3 months.

- Tobacco amblyopia and Leber's optic atrophy:
  Initially 1000 micrograms (1 ampoule) or more daily for 2 weeks, then twice weekly for as long as improvement is noticed.
  Maintenance dose: 1000 micrograms (1 ampoule) monthly.

Instruction to open the ampoule:
1. Hold the ampoule body between your thumb and index finger, with the point facing upwards;
2. Put your other hand index finger supporting the upper part of the ampoule. Put your thumb over the point;
3. With your index fingers close to each other, press the point area to open the ampoule.



Medical check-ups
While you are receiving this medicine, your doctor will want you to have regular blood tests to check your condition. This is to make sure that your medicine is working properly and that the dose you are receiving is right for you.

If you are given more Hydroxocobalamin solution for injection than you should
If you think you have been given too much Hydroxocobalamin solution for injection, you are unlikely to need any special treatment. However, if you suffer any discomfort or side effects you should tell your doctor.
If you have any further questions about the use of this medicine, ask your doctor, pharmacist 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, these symptoms can be serious.
- **swelling of the lips, tongue or throat, 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 possible side effects (frequency not known):
- Acne-like rash;
- Blisters;
- Pain at the injection site;
- Feeling of "pins and needles";
- Feeling unwell or sick;
- Being sick;
- Diarrhoea;
- Dizziness;
- Headache;
- Fever;
- Chills;
- Hot flushes;
- Pain;
- Unusually coloured urine;
- Too many platelets in the blood.

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 Yellow Card Scheme Website: 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 to store Hydroxocobalamin solution for 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 ampoule and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25 ºC.

The product should not be used if it is not a clear red solution or if it contains visible particles.
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 1000 micrograms/ml solution for injection contains
- The active substance is hydroxocobalamin. Each 1 ml ampoule contains 1027 micrograms of hydroxocobalamin chloride, equivalent to 1000 micrograms of hydroxocobalamin.
- The other ingredients are sodium chloride, glacial acetic acid and water for injection.

What Hydroxocobalamin 1000 micrograms/ml solution for injection looks like and contents of the pack
Hydroxocobalamin solution for injection is a clear, red sterile solution, free of visible particles, presented in type I colourless glass ampoules of 1 ml.
Pack size: 5 or 10 ampoules.

Marketing Authorisation Holder
Gemapharm Ltd
5 Merchant Square,
Paddington, London
W2 1AY, UK
Tel.: +44 (0) 208 049 0777
E-mail: info@gemapharm.org

Manufacturer
Laboratórios Basi - Indústria Farmacêutica S.A.
Parque Industrial Manuel Lourenço Ferreira
Lotes 8, 15 e 16
3450-232 Mortágua
Portugal

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CLIENT Gemapharm Ltd. | TEC. - | DATE -
PRODUCT Hydroxocobalamin 1000 micrograms/ml Sol. Inj. | PMTS 236
UPDATES -
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mm 140 560 140 x 35 4 15 50 g/m² | Black, Cutter Guide
mm A 000 B 000 H 000 000 g/m²
Outlined Text
mm 1,4 | mm 000 x 000
mm 3,2 | mm 0
MOD.595_8
gemapharm
PRODUCT MANAGEMENT
OTHER DEPARTMENTS
CLIENT