

Package leaflet: Information for the user

Hydroxocobalamin Basi 1000 microgram/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, pharmacist 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, 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 Basi is and what it is used for
2. What you need to know before you use Hydroxocobalamin Basi
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1. What Hydroxocobalamin Basi is and what it is used for

Hydroxocobalamin Basi is a form of Vitamin B12, an essential vitamin which is needed for production of red blood cells.

Hydroxocobalamin Basi 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.

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

Do not use Hydroxocobalamin Basi

- 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

Talk to your doctor, pharmacist or nurse before you using Hydroxocobalamin Basi.

Check with your doctor if:

- you are pregnant, planning to become pregnant or breast-feeding;
- you have megaloblastic anaemia. This is a blood disorder characterized by the presence of larger than normal blood cells.

Other medicines and Hydroxocobalamin Basi

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

Particularly, 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 it can reduce the effect of Hydroxocobalamin Basi;
- Oral contraceptives.

Pregnancy and breast-feeding

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 Basi should not be used in pregnancy for treating a kind of anaemia called megaloblastic anaemia, unless you also have a Vitamin B12 deficiency.

Hydroxocobalamin Basi passes into the breast-milk, but it is unlikely that it will harm your baby.

Driving and using machines

This medicine is unlikely to affect your ability to drive or to operate machinery. However, some people may feel dizzy or drowsy when treated with hydroxocobalamin. If this happens to you, do not drive or use machines.

Hydroxocobalamin Basi contains sodium

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

3. How to use Hydroxocobalamin Basi

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

Hydroxocobalamin Basi will be given to you through an injection into a muscle. Your doctor will choose the dose that is right for you. This medicine may be administered to you just once or it may be repeated every other day, weekly or monthly, depending on how much your body needs.

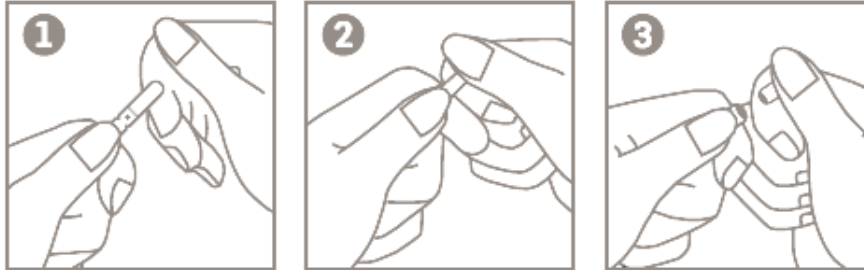
The recommended doses in severe conditions, by deep injection into a muscle, are as follows:

Adults and Children

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

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 being treated with this medicine, your doctor will want you to have regular blood tests. This is to make sure that your medicine is working properly and that the dose you are receiving is right for you.

If you use more Hydroxocobalamin Basi than you should

If you think you have been using too much Hydroxocobalamin Basi, 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 on 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.

Stop using Hydroxocobalamin Basi and tell your doctor immediately if you have any of the following symptoms:

- **Difficulties in breathing;**
- **Swelling of your eyelids, face or lips;**
- **Rash or itching especially those covering your whole body.**

Other side effects

Not known: frequency cannot be estimated from the available data

- Low blood potassium levels and irregular heart beat during the early stages of treatment;
- Thrombocytosis (high number of platelets in your blood);
- Rash;
- Blisters;
- Pain at the site of injection;
- Hardening of the skin at the site of injection;
- Necrosis (destruction of the skin) around the injection site;
- Pins and needles;
- Feeling unwell or sick;

- Being sick;
- Diarrhoea;
- Pink or red coloured urine;
- Dizziness;
- Headache;
- Tremor;
- Fever;
- Chills;
- Hot flushes;
- Pain.

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 HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Hydroxocobalamin Basi

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 25°C.

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 Basi contains

- The active substance is hydroxocobalamin. Each ampoule of 1 ml contains hydroxocobalamin chloride equivalent to 1000 microgram hydroxocobalamin.
- The other ingredients are sodium chloride, glacial acetic acid and water for injections.

What Hydroxocobalamin Basi looks like and contents of the pack

Hydroxocobalamin Basi is a clear, red solution, free of visible particles, presented in glass ampoules. Pack size: 5 and 10 ampoules of 1 ml.

Marketing Authorisation Holder

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Manufacturer

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

Portugal: Hidroxocobalamina Basi

Ireland: Hydroxocobalamin Basi 1000 microgram/ml solution for injection

Norway: Hydroxocobalamin Basi

Spain: Hidroxocobalamina Basi 1 mg/ml solución inyectable

This leaflet was last revised in