Patient Information Leaflet

Neo-Cytamen® 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 or nurse.
- 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

In this leaflet:
1. What Neo-Cytamen is and what it is used for
2. What you need to know before you are given Neo-Cytamen
3. How you will be given Neo-Cytamen
4. Possible side effects
5. How to store Neo-Cytamen
6. Contents of the pack and other information.

1. What Neo-Cytamen is and what it is used for
Neo-Cytamen 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.

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 deterioration of eyesight and loss of central vision.

In this leaflet, Neo-Cytamen® 1000 micrograms/ml solution for injection will be called Neo-Cytamen.

2. What you need to know before you are given Neo-Cytamen
You should not be given Neo-Cytamen if:
- You are allergic to the active ingredient, hydroxocobalamin
- You are allergic to any of the other ingredients of Neo-Cytamen (see section 6.).

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

Check with your doctor before being given Neo-Cytamen if:
- You are pregnant, planning to become pregnant or breast-feeding
- You have megaloblastic anaemia. This is a blood disorder where you have larger than normal blood cells.

If you have a known cobalt allergy talk to your nurse or doctor. Hydroxocobalamin contains cobalt.

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 Neo-Cytamen
• Oral contraceptives 'The Pill'
• Any other medicine, including medicines obtained without a prescription.
If any of the above applies to you talk to your doctor or nurse.

Pregnancy and breast-feeding
Neo-Cytamen should not be used in pregnancy for treating a kind of anaemia called megaloblastic anaemia, unless you also have a vitamin B12 deficiency.

Neo-Cytamen is found in breast-milk but it is unlikely that it will harm your baby.

If you are pregnant, trying to become pregnant or are breast-feeding, ask your doctor or nurse for advice before being given Neo-Cytamen.

Driving and using machines
Neo-Cytamen may cause dizziness. If this happens to you, do not drive or use machinery.

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

3. How you will be given Neo-Cytamen
Neo-Cytamen 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 Neo-Cytamen by your doctor or nurse as an injection into a muscle. 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 every 2 to 3 months.
- With neurological involvement: 1000 micrograms every other day for as long as improvement is noticed.
Maintenance dose: 1000 micrograms every 2 months.
• Prevention of anaemia: 1000 micrograms every 2 to 3 months.
• Tobacco amblyopia and Leber's optic atrophy:
- Initially 1000 micrograms or more daily for 2 weeks, then twice weekly for as long as improvement is noticed.
- Maintenance dose: 1000 micrograms monthly.

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 Neo-Cytamen than you should
If you think you have been given too much Neo-Cytamen, 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 or nurse.

4. Possible side effects
What Neo-Cytamen contains
Like all medicines Neo-Cytamen 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)

• A high number of platelets in your blood
• Acne-like rash
• Blisters
• Pain at the site of injection
• The skin may become hard at the site of injection
• The skin around the injection site may die.
• Feeling of '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 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 Neo-Cytamen
Keep out of the sight and reach of children.

Do not use Neo-Cytamen after the expiry date which is stated on the label (EXP). The expiry date refers to the last day of the month.
Do not store above 25ºC. Keep Neo-Cytamen ampoules in the outer carton in order to protect from light.
Your doctor or nurse will make sure your medicine is correctly stored and disposed of.

6. Further information

What Neo-Cytamen contains

Each 1 ml ampoule contains 1000 micrograms of the active ingredient hydroxocobalamin (as hydroxocobalamin chloride
The other ingredients are sodium chloride, glacial acetic acid and water for injection.

What Neo-Cytamen looks like

Neo-Cytamen® 1000 micrograms/ml Solution for Injection is a clear red-brown solution.
Do not use Neo-Cytamen Injection if you notice that the solution is not a clear red-brown colour or if the solution contains particulate matter.
It comes in packs of 5 ampoules.

Marketing Authorisation Holder

RPH Pharmaceuticals AB, Box 603, 101 32 Stockholm, Sweden.

Manufacturer

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This leaflet was last revised in September 2024
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If this leaflet is difficult to see or read or you would like it in a different format, please contact: RPH Pharmaceuticals AB, Box 603, 101 32 Stockholm, Sweden.