

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

In this leaflet:

1. What Neo-Cytamen is for
2. 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. Further information.

1. What Neo-Cytamen is for

Neo-Cytamen is a form of Vitamin B12, an essential vitamin which is needed for production of red blood cells.

Neo-Cytamen 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.

2. 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.

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.

Important information about some of the ingredients of Neo-Cytamen Injection

This medicinal product contains less than 1mmol sodium (23mg) per 1000 micrograms/ml, i.e. essentially sodium free.

3. How you will be given Neo-Cytamen

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.

Stop using Neo-Cytamen and seek immediate medical help if you have an allergic reaction.

This includes any of the following symptoms:

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

Effects on the heart and blood

- Low blood potassium levels and irregular heart beat during the early stages of treatment
- Thrombocytosis (where you have a high number of platelets in your blood)

Effects on the eyes and skin

- 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'

Effects on the stomach and bowel

- Feeling unwell or sick
- Being sick
- Diarrhoea
- Pink or red coloured urine.

Effects on the nervous system

- Dizziness
- Headache
- Tremor

Other effects

- 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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971. Fax: +353 1 6762517. Website: www.hpra.ie e-mail: medsafety@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 25°C. 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

The active substance is hydroxocobalamin at a strength of 1000 micrograms (1 mg) per ml of solution. Each ml contains hydroxocobalamin chloride 1.027mg, equivalent to hydroxocobalamin 1.0mg.

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 sterile solution.

Do not use Neo-Cytamen Injection if you notice that the solution is not a clear redbrown colour or if the solution contains particulate matter.

It comes in packs of 5 ampoules, each containing 1 ml of solution.

Marketing Authorisation Holder

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

Manufacturer

Wasserburger Arzneimittelwerk GmbH Herderstraße 2, D-83512 Wasserburg, Germany.

This leaflet was last updated June 2021.

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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.