

Patient Information Leaflet: Cytamen® 1000 micrograms/ml Injection Cyanocobalamin

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, Cytamen® 1000 micrograms/ml Solution for Injection will be called Cytamen.

In this leaflet:

1. What Cytamen is for
2. Before you are given Cytamen
3. How you will be given Cytamen
4. Possible side effects
5. How to store Cytamen
6. Further information.

1. What Cytamen is for

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

Vitamin B12 contains cobalt.

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 for a test called the Schilling Test, which measures your ability to absorb Vitamin B12 from the bowel.

2. Before you are given Cytamen

You should not be given Cytamen if:

- You are allergic to the active ingredient, cyanocobalamin
 - You are allergic to any of the other ingredients of Cytamen (see section 6.)
 - You have a condition called toxic amblyopia (poor vision which may be due to Vitamin B12 deficiency).
- If any of the above applies to you talk to your doctor or nurse.

Check with your doctor before being given 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

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

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 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

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

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 Cytamen.

Driving and using machines

Cytamen may cause dizziness. If this happens to you, do not drive or use machinery.

Cytamen contains sodium chloride

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

3. How you will be given Cytamen Important:

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

You will be given 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 month.
- With neurological involvement: 1000 micrograms every other day for as long as improvement is noticed. Maintenance dose: 1000 micrograms every month.

• Prevention of anaemia:

- 250 -1000 micrograms every month.

• Schilling Test:

- 1000 micrograms.

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 Cytamen than you should

If you think you have been given too much 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

Like all medicines Cytamen can cause side effects, although not everybody gets them.

Stop using 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.

Effects on the stomach and bowel

- Feeling unwell or sick

Effects on the nervous system

- Dizziness
- Tremor

Other effects

- Fever
- Chills
- Hot flushes
- Pain.

Reporting of side effects

If you get any side effects, talk to your doctor 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 Cytamen

Keep this medicine out of the sight and reach of children.

Do not use Cytamen after the expiry date on the label. The expiry date refers to the last day of that month.

Store below 25°C. Keep Cytamen in the original packaging in order to protect it from light.

Your doctor or nurse will make sure your medicine is correctly stored and disposed of.

6. Further information

What Cytamen contains

The active substance is cyanocobalamin at a strength of 1000 micrograms (1 mg) per ml of solution.

The other ingredients are sodium chloride, acetic acid and water for injection.

What Cytamen looks like

Cytamen® 1000 micrograms/ml Injection is a sterile solution. 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 revised in 08/2024

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If this leaflet is difficult to see or read or you would like it in a different format, please contact:
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