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PACKAGE LEAFLET: INFORMATION FOR THE USER

VITAMIN B12 1mg/1ml

Solution for injection / oral solution
Cyanocobalamin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you.

You may receive this medicine without medical prescription. But use it cautiously to obtain the better effects.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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 must talk to a doctor if you do not feel better or if you feel worse after several days.

What is in this leaflet

1. What VITAMIN B12 1mg/1ml is and what it is used for
2. What you need to know before you use VITAMIN B12 1mg/1ml
3. How to use VITAMIN B12 1mg/1ml
4. Possible side effects
5. How to store VITAMIN B12 1mg/1ml
6. Contents of the pack and other information

1. WHAT VITAMIN B12 1mg/1ml IS AND WHAT IT IS USED FOR:

Cyanocobalamin or vitamin B12 plays a significant role in the metabolism of every cell in the body.

Therapeutic indications:

Treatment of vitamin B12 deficiency and the anemia it causes. Vitamin B12 deficiency can be prevented by a balanced diet ; however, with certain types of anemia or in people who are unable to absorb the vitamin from the food they eat, dietary sources are not sufficient.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE VITAMIN B12 1mg/1ml:

Do not use Vitamin B12 1mg/1ml

- If you are allergic to vitamin B12 or cyanocobalamin or any of the other ingredients of this medicine (listed in section 6).
- If the solution is not clear.
- If you have a history of allergy to cobalamins (vitamins B12 and related substances).
- If you suffer from optic nerve degeneration.
- If you have a malignant tumor.
- Vitamin B12 cannot be used before the type and cause of the anemia must be firmly established.

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- Use of folic acid in patients with vitamin B12 deficiency is formally contraindicated since it may cause a fulminant neurological deficit.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Vitamin B12 1mg/1ml

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- Before starting treatment, tell the doctor if you have allergic tendencies, for example, if you have asthma or eczema, because you may also be allergic to vitamin B12 and the doctor must take this into account.

- As the administration of cyanocobalamin may mask pernicious anemia, it is important to have the diagnosis confirmed by your doctor before treatment.

- When you administer Vitamin B12 1mg/1ml as this medicine does not contain any antimicrobial preservatives and will therefore not prevent growth of microorganisms.

The medicinal solution must be withdrawn as recommended in current good practices, using optimally aseptic technique, into a sterile syringe and immediately after the ampoule is opened. The medicinal solution and any syringe containing the solution are for single and individual use only.

Any unused or remaining solution must be disposed of as described in current good practices.

If you already use other drugs, please read also the section "Other medicines and VITAMIN B12 1mg/1ml".

Other medicines and Vitamin B12 1mg/1ml

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

When co-administered with nitrogen protoxide (laughing gas) which is used for anesthesia (particularly in dentistry), the activity of the vitamin B12 decreases.

Vitamin B12 1mg/1ml with food, drink and alcohol
Not applicable.

Pregnancy, breast-feeding and fertility

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.

If you are pregnant or breastfeeding, this product will be used only after medical advice.

Driving and using machines

Vitamin B12 has no influence on the ability to drive and use machines.

Vitamin B12 1mg/1ml contains no ingredients called for any particular remarks.

3. HOW TO USE VITAMIN B12 1mg/1ml

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

Vitamin B12 is a red solution for injection / oral solution for administration by subcutaneous,

intramuscular, intravenous or oral route. The intramuscular route is to be preferred.

The solution can be diluted in a glass of water and drunk or injected directly.

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It is difficult to calculate the doses of vitamin B12 required as treatment should be aimed at replenishing the liver reserves (3000 to 10 000 µg). In addition, the amount of vitamin B12 retained by the body decreases as these liver reserves increase.

Use of the intramuscular route at the start of treatment is recommended. Maintenance treatment can be administered via the

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vitamin B12 or pernicious anemia. In such cases, intramuscular therapy must be continued life-long. Serum vitamin B12 levels, compliance with treatment and treatment efficacy should all be monitored regularly.

Adults:

Vitamin B12 deficiency with no clinical complications (ex. pernicious anemia and malabsorption)

- By injection:

. Loading dose: administer 1 ampoule (1mg) per day or 3 ampoules a week to be repeated depending on the blood test results.

. Maintenance dose: administer 1 ampoule (1mg) per month.

- By oral route:

. Loading dose: take 1 ampoule (1mg) per day for two weeks to one month.

. Maintenance dose: take 1 ampoule (1mg) every 10 days.

Vitamin B12 deficiency with clinical complications (for example: secondary neuropathy caused by vitamin B12 deficiency)

- By injection:

. Loading dose: administer 1 ampoule (1mg) per day until the clinical symptoms improve.

. Maintenance dose: administer 1 ampoule (1mg) per month.

Prevention of vitamin B12 deficiency (for example: after gastrectomy or malabsorption syndrome) 200 µg to 1000 µg/month or every two months may be required.

Use in case of severe renal insufficiency

In patients with severe renal insufficiency, it may be possible to increase the dose (or reduce the interval between doses) as the response to vitamin B12 treatment may be reduced in these patients.

Use in case of liver insufficiency

In patients with liver insufficiency, it may be possible to lengthen the interval between doses during maintenance treatment.

Pediatric doses:

The use and safety of vitamin B12 have not yet been investigated in young children and teenagers.

If you use more Vitamin B12 1mg/1ml than you should, immediately contact your doctor, your pharmacist or your Healthcare Authority).

A vitamin B12 overdose is not possible as the excess administered is eliminated naturally from the body.

Normally, you will not observe any symptoms if you take too much of the medicine.

oral route except in patients with irreversible malabsorption of **Page 4**

Shock, which is very rare, should be treated with vasopressor medicines and injectable corticoids under the supervision of a doctor.

If you forget to use Vitamin B12 1mg/1ml, this should not comprise a risk for your health.

Do not take a double dose to make up for a forgotten dose.

If you stop using Vitamin B12 1mg/1ml

Always consult your doctor if you plan to stop taking your treatment.

If you stop your treatment before the end of the course prescribed for you, you may experience symptoms of anemia, the most common of which is unexplained fatigue.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

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

The frequency of the potential side effects is as follows:

- Very common : affects more than one in ten patients
- Common : affects 1 to 10 in every 100 patients
- Uncommon : affects 1 to 10 in every 1,000 patients
- Rare : affects 1 to 10 in every 10,000 patients
- Very rare : affects less than 1 in every 10,000 patients
- Not known : frequency cannot be estimated from the available data.

The following side effects may arise during treatment with Vitamin B12 :

Common :

- Red coloration of urine, which has no particular significance.

Very rare :

- Anaphylactic shock

Not known :

- Anaphylactic reactions: pruritus, urticaria, erythema

- Risk of acne

- Possibility of pain at the injection site

If you get any side effects, talk to your doctor, pharmacist or nurse.

This includes any side effects not listed in this leaflet.

5. HOW TO STORE VITAMIN B12 1mg/1ml

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

Protect from light/direct sunlight and high temperatures.

Do not use this medicine after the expiry date which is stated on the vial after "EXP. The expiry date refers to the last day of that month.

Manufactured by ANB Labs Ramintra Road, Thailand.
www.anblab.com