Cernevit

Multivitamin injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Cernevit Multivitamin [Cernevit]. It does not contain all of the available information. All medicines have risks and benefit. Your doctor has weighed the risks of you using Cernevit against the expected benefit.

It does not take the place of talking to your doctor or pharmacist.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine, as you may need to read it again.

What Cernevit is used for

The brand name of your medicine is Cernevit, which belongs to the vitamins, mineral and other nutritional supplements group of medicines. It is a multivitamin preparation of both water and fat-soluble vitamins (without Vitamin K) stabilised with a mixture of solubilising agent. This medicine is used as a multivitamin supplement corresponding to the daily needs of adults and children (over 11 years of age). As Cernevit is an injectable preparation, it is therefore intended to be given as an injection or infusion directly into the vein (intravenously).

What should you know before the use of Cernevit

Cernevit should not be given to you if:

- You have had an allergic reaction to any of the ingredients of Cernevit listed in the Ingredients section of this leaflet, especially thiamine (Vitamin B_1). Some of the symptoms of an allergic reaction may include skin rash, peeling of the skin, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing or shortness of breath.
- You have an impairment with liver function. You are suffering from hyperparathyroidism due to abnormally elevated calcium levels in the blood.
- The expiry date (EXP) printed on the pack is overdue.
- You are not sure whether you should be given Cernevit injection.

You must tell your doctor if:

- You are allergic to thiamine (Vitamin B_1), nicotinamide components of this product, any other medicines, foods, dyes, or preservatives.
- You have any other health problems including:
  - Kidney disease
  - Active inflammatory bowel disease
  - You are currently receiving Vitamin A from another source
  - Liver disease
- You are pregnant or intend to become pregnant, as it is not known whether Cernevit may cause harm to the foetus. Your doctor will discuss with you the risks and benefits of giving this product during pregnancy.
- You are breast-feeding or wish to breast-feed, as it is known that vitamins are excreted in breast milk. Your doctor will discuss with you the risks and benefits of giving Cernevit injection to a nursing mother.
- You are taking prescription medicines, such as antiepileptic drugs; phenobarbitol, primidone and phenytoin (with brand name Dilantin). The effectiveness of the active component in antiepileptic drugs is affected by folic acid, one of the vitamins included in the Cernevit formulation. Several vitamins can decrease the effectiveness of antibiotics, such as bleomycin and the tetracycline family.
- You are taking prescription medicines or tablets for heart or blood pressure or levodopa for the treatment of Parkinson's disease.
- You are taking any non-prescription medicine purchasing from your pharmacy, supermarket or health food shop.

How is Cernevit given

How much is given:

Your doctor will decide when and how much Cernevit will be given to you, which is normally 1 (one) vial per day for adults and children aged over 11 years.

How will it be given:

Your doctor will inject the medicine into you. Cernevit injection will be given to you as a slow injection after it has been mixed with drip solutions, directly into the vein (intravenously) by your doctor or trained nurse.

How long will it be given:

Your doctor will determine the duration of your treatment, which will depend on your need.

Side Effects

Most people who receive this medicine do not experience side effects. However, as with most medicines, Cernevit can sometimes cause unwanted side effects. Allergic reactions have been known to occur following intravenous injection of Vitamin B_1. To date, that there have been no reports on fatal allergic reactions associated with this product.

However, you must tell your doctor or pharmacist as soon as possible if you do not feel well while you are treated with Cernevit you are having a sign of allergic reactions, as shown in any form of the following sign:

- Swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing.
- Flushing, itching or burning of the skin, sneezing/hives or mild asthma-like attacks.
- Yellowing of the skin and eyes, also called jaundice.

All of these side effects are very rare, but if you have them, you may have had a serious allergic reaction. Stop taking Cernevit or go to accident and emergency at your nearest hospital.

Overdose

To date little is known about experience on overdose symptoms with Cernevit. However, a prolonged use of vitamin A and D with a high dosing, two of the components of this product, hypervitaminosis A and D may appear. In cases of suspected overdose, symptomatic and supportive treatments should be given as appropriate, and the treatment with Cernevit should be discontinued.

Storage Conditions

Cernevit should be stored below 25ºC and protected from light and heat. Do not freeze.

Product Descriptions

What Cernevit looks like:

Cernevit is presented as an orange-yellow powder contained in a brown glass vial, closed with elastomer closures and crimped by aluminium cap. Each vial is accompanied by ampoule containing 5 mL of water for injection. Your doctor or trained nurse will reconstitute it with the provided water for injection prior to the infusion or injection of your medicine.

Ingredients:

Each vial of Cernevit contains the following components:

Active ingredients

- Retinol/Vitamin A (3500 IU),
- Cholecalciferol/Vitamin D_3 (220 IU (is 5.5 µg the equivalent of 220 IU?)),
- Alpha-tocopherol/Vitamin E (10.20 mg),
- Ascorbic acid/Vitamin C (125 mg),
- Thiamine/Vitamin B_1 (3.51 mg),
- Riboflavin/Vitamin B_2 (4.14 mg),
- Pyridoxine/Vitamin B_6 (4.53 mg),
- Cyanocobalamin/Vitamin B_{12} (6 µg),
- Folic acid (414 µg),
- Pantothenic acid (17.25 mg),
- Biotin (69 µg),
- Nicotinamide (46 mg).

Inactive Ingredients

- Glycine (250 mg),
- Glycocholic acid (140 mg),
- Soybean lecithin (112.5 mg),
- Sodium chloride resulted from pH 5.9 adjustment with Sodium hydroxide.

Manufacturer

Cernevit is manufactured by **Baxter/Clintec Parenteral** in France and supplied in Australia by:

Baxter Healthcare Pty Ltd.
1 Baxter Drive,
Old Toongabbie, NSW 2146, Sydney

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