Cernevit

Multivitamin powder for injection

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about Cernevit Multivitamin powder for injection.

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 benefit they expect it will have for you.

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

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

Keep this leaflet;
you may need to read it again.

What Cernevit is used for?

This medicine 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 your daily needs and is given as an injection or infusion directly into the vein (intravenously).

Before you are given 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) or soy/protein products. 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 has passed.

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 additional vitamins from any other sources, especially with Vitamin A, D and E
  - 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 medications containing theophylline, tipranavir or vitamin K antagonists, such as warfarin.
- You are taking any other medicines including any that you get without a prescription from your pharmacy, supermarket or health food stores, in particular for heart or blood pressure or levodopa for the treatment of Parkinson's disease.

How is Cernevit given?

How much is given:

Your doctor will decide when and how much Cernevit will be given to you, which depends on your need and condition.

How is it 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.

This medicine is for single use and for one person only. Any unused portion must be discarded and not used later, either for you or anyone else.

How long will it be given:

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

Case of overdose

The doctor or nurse giving you Cernevit has had experience in the use of this sort of medicine, so it is unlikely that you will be given an overdose. However, in case of an overdose, the Cernevit treatment will be discontinued and another treatment may be needed. You may experience some of the effects listed under "Side Effects" below.

Side Effects

As with any medicines, some side effects may occur. Allergic reactions have been known to occur following intravenous injection of Vitamin B_1.

Always tell your doctor or nurse if you have any unexpected effects during or after receiving Cernevit and they worry you, including:

- 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.
- Breathing difficulties
- Faster heart beat
- Diarrhea

Storage Conditions

Cernevit should be stored below 25°C and protected from light and heat.

Do not freeze.

Product Description

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 as retinyl palmitate (3500 IU),
- cholecalciferol (5.5 μg),
- dl-alpha-tocopherol (10.20 mg),
- ascorbic acid (125 mg),
- cocarboxylase tetrahydrate (5.80 mg),
- riboflavin sodium phosphate (5.67 mg),
- pyridoxine hydrochloride (5.50 mg)
- cyanocobalamin (6 μg),
- folic acid (414 μg),
- dexpanthenol (16.15 mg),
- biotin (69 μg),
- nicotinamide (46 mg).

Other ingredients

Glycine, glycocholic acid, lecithin, sodium hydroxide and/or hydrochloric acid.

Name and Address of Sponsor

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

Australian Registration number
AUST R 92418

Date of preparation:
March 2016