Baxter

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

CERNEVIT Powder for Solution for Injection or Infusion

Read all of this leaflet carefully before this medicine is given to you because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

Throughout this leaflet CERNEVIT Powder for Solution for Injection or Infusion will be called CERNEVIT.

1 What CERNEVIT is and what it is used for

CERNEVIT is a powder for solution for injection or infusion. It contains 12 vitamins (see Section 6).

CERNEVIT is used to give your daily requirement of vitamins straight into your blood. It is used when you cannot take enough food by your mouth. It is usually given with other things such as nutrition solutions and minerals.

2 What you need to know before CERNEVIT is given

You will NOT be given CERNEVIT if:

- you are allergic (hypersensitive) to the active substance or any of the ingredients of this medicine, especially vitamin B1 or soy protein or peanut protein (see Section 6, Contents of the pack and other information),
- you have too much of one of the vitamins in CERNEVIT stored in your body (called 'hypervitaminosis').

Do not have CERNEVIT if any of the above applies to you. If you are not sure talk to your doctor, nurse or pharmacist.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given CERNEVIT if:

- you are having vitamin A (retinol) from other sources
- you have kidney problems. In this case your doctor will carefully monitor your fat-soluble vitamin levels. The fat-soluble vitamins are A, D, E and K
- you have liver disease. Your doctor will do blood tests to check how well your liver is working. They will monitor the levels of certain 'enzymes' in your liver.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before being given CERNEVIT.

Your doctor will make sure that:

- you are given additional vitamin K if you need it. CERNEVIT does not contain vitamin K
- your body has all that it needs for good health. If necessary, you may also be given minerals, amino acids (the building blocks of protein), fatty acids (the building blocks of fats), electrolytes (salts) and sugar solutions (such as glucose).

Other medicines and CERNEVIT

Please tell you doctor, nurse or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

This is because some of the ingredients in CERNEVIT can affect the way some medicines work.

In particular tell your doctor, nurse or pharmacist if you are taking any of the following medicines.

- Levodopa (a medicine used for Parkinson's disease). The vitamin B_6 (pyridoxine) in CERNEVIT can affect this medicine
- Phenobarbital, phenytoin and/or primidone (used in epilepsy for fits or convulsions and sometimes for other conditions). The folic acid in CERNEVIT may interact with these medicines.

Your doctor may monitor the levels of these medicines in your blood and may have to adjust their dose when you start or stop taking CERNEVIT.

Tests while you are having CERNEVIT

CERNEVIT contains 69 µg biotin per vial (5 mL). If you are about to undergo laboratory testing you must tell your doctor or the laboratory personnel that you are taking or have recently taken CERNEVIT, because biotin may affect results of such tests. Depending on the test, the results may be falsely elevated or falsely low due to biotin. Your doctor may ask you to stop taking CERNEVIT before performing laboratory tests. You should also be aware that other products that you may take, such as multivitamins or supplements for hair, skin, and nails could also contain biotin and affect the results of laboratory tests. Please inform your doctor or the laboratory personnel, if you are taking such products.

If you are due to have a urine or a blood test, tell your doctor you are having CERNEVIT:

- Ascorbic acid may interfere with urine and blood glucose testing systems.
- The folic acid in CERNEVIT may stop the detection of a problem called 'pernicious anaemia'. This is when you have a drop in red blood cells because your body cannot properly absorb vitamin B_{12} from your gut.

Important Information about some of the ingredients of CERNEVIT

CERNEVIT contains 24 mg sodium (1 mmol) per vial. This should be taken into consideration by patients on a controlled sodium diet.

Fertility, pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
You may receive CERNEVIT during pregnancy if required, providing the indication and dosages are observed to avoid vitamin overdose.

Breast-feeding
The use of CERNEVIT is not recommended if you are breast-feeding. If you breast-feed whilst taking CERNEVIT there is a danger that your baby could get an overdose of vitamin A.

Fertility
No data are available on the effect of CERNEVIT on male or female fertility.

3 How CERNEVIT is given

CERNEVIT will be given to you by a doctor or nurse.

How CERNEVIT is given
- The CERNEVIT powder will first be dissolved with a liquid such as 'sterile water for injection'. This will be mixed with a larger volume of fluid before it is given to you.
- It will be given into a vein as a drip (slow intravenous infusion) over at least ten minutes.
- CERNEVIT can also be added to other nutrition solutions. This mixed nutrition solution will be given to you as a drip into your vein.

The recommended dose
Your doctor will decide how much CERNEVIT you should be given. The amount you will be given depends upon your age, weight and the reason you are being given the medicine.
- **Adults and children over 11 years:** the recommended dose is one vial (small glass bottle) of CERNEVIT each day.
- **Children under 11 years:** not recommended.

If you are given too much
Your doctor or nurse will give you CERNEVIT so it is unlikely you will be given too much. If you are worried that you have had too much, tell your doctor or nurse.

Signs of overdose of CERNEVIT are mostly the signs of overdose of vitamin A:

- Signs of sudden overdose of vitamin A include:
  - gastrointestinal disorders (nausea, vomiting),
  - nervous system disorders (headache, swelling of the optic nerve, convulsions) due to an increased pressure in your head,
  - psychiatric disorders (irritability),
  - skin disorders (delayed peeling of the skin).
- Signs of long-term overdose of vitamin A include:
  - headache due to an increased pressure in your head,
  - bone disorders (tender or painful swellings at the ends of your limbs).

If you notice any of these signs of overdose, tell your doctor or nurse. They may stop your CERNEVIT infusion.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

The following side effect is common and could affect 1 to 10 users in 100:

- Pain at the site of injection

The following side effects are uncommon and could affect 1 to 10 users in 1,000:

- Feeling sick (nausea),
- being sick (vomiting)

The following side effects have been reported at an unknown frequency:

- Allergic reactions, with respiratory difficulties, chest pain, tightening of the throat, urticaria, rash, skin redness, abdominal discomfort, as well as cardiac arrest
- Increased levels of vitamin A and vitamin A carrier protein in blood
- Taste alteration (metallic taste)
- Accelerated heart rate
- Accelerated breathing rate
- Diarrhoea
- Increase in level of liver enzymes and bile acid
- Pruritus (itching)
- Fever, generalized soreness, reactions at the site of infusion such as burning sensation, rash.

If you show any symptom of an allergic reaction such as respiratory difficulties, chest pain, tightening of the throat, urticaria, rash, skin redness, abdominal discomfort, inform a doctor or nurse immediately. They will stop the infusion and conduct the necessary emergency measures.

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme
www.mhra.gov.uk/yellowcard

5 How to store CERNEVIT

Because CERNEVIT is usually given in hospital it will be stored safely and correctly by the hospital staff. If you do need the storage conditions they are given below.

- Keep this medicine out of the sight and reach of children.
- This medicine will not be used after the expiry date that is stated on the label after 'EXP'. The expiry date refers to the last day of that month.
- Do not store above 25ºC.
- Store in the outer carton in order to protect from light.
- CERNEVIT should not be used if the solution is not clear, or if the vial is damaged in any way.
- Once CERNEVIT has been mixed with water it should not be kept for more than 24 hours at 2 to 8°C, unless otherwise specified by your doctor.
- Partly used vials should not be used again. Any left-over CERNEVIT should be thrown away safely by a healthcare professional.
- All equipment used will be disposed of safely by a healthcare professional after use.

6 Contents of the pack and other information

What CERNEVIT contains

- The active substances are retinol palmitate (vitamin A) 3500 IU, colecalciferol (vitamin D_3) 220 IU, DL-α-tocopherol (vitamin E) 10.20 mg, ascorbic acid (vitamin C) 125 mg, cocarboxylase tetrahydrate (vitamin B_1) 5.80 mg, riboflavin dihydrated sodium phosphate (vitamin B_2) 5.67 mg, pyridoxine hydrochloride (vitamin B_6) 5.50 mg, cyanocobalamin (vitamin B_{12}) 6 µg, folic acid 414 µg, dexpanthenol 16.15 mg, D-Biotin 69 µg, nicotinamide (vitamin PP) 46 mg per vial.

  IU = International Units
  mg = milligrams
  µg = micrograms

- The other ingredients are glycine, glycocholic acid and soybean phosphatides. It may also contain small amounts of sodium hydroxide or hydrochloric acid for pH adjustment.

What CERNEVIT looks like and the contents of the pack
CERNEVIT is a powder for solution for injection or infusion. It is an orange-yellow cake of powder supplied in brown glass vials. It is packaged in cartons containing 1, 10 or 20 vials. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
The Marketing Authorisation holder is:
Baxter Healthcare Ltd
Caxton Way, Thetford, Norfolk, IP24 3SE
United Kingdom

Send all enquiries to this address.

CERNEVIT is made at:
Baxter S.A.
Bd. R. Branquart 80, 7860 Lessines
Belgium

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For information about CERNEVIT or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder: Tel: 01635 206345.