

## 6 Further information

### What CERNEVIT contains

- The active substances are retinol palmitate (vitamin A) 3500 IU, colexcalciferol (vitamin D<sub>3</sub>) 220 IU, DL- $\alpha$ -tocopherol (vitamin E) 10.20 mg, ascorbic acid (vitamin C) 125 mg, cocarboxylase tetrahydrate (vitamin B<sub>1</sub>) 5.80 mg, riboflavin dehydrated sodium phosphate (vitamin B<sub>2</sub>) 5.67 mg, pyridoxine hydrochloride (vitamin B<sub>6</sub>) 5.50 mg, cyanocobalamin (vitamin B<sub>12</sub>) 6  $\mu$ g, folic acid 414  $\mu$ g, dexpanthenol 16.15 mg, D-Biotin 69  $\mu$ g, nicotinamide (vitamin PP) 46 mg per vial.
- 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, B-7860 Lessines  
Belgium

This leaflet was last approved in July 2010.

**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.**

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# 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.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

#### In this leaflet:

- 1 What CERNEVIT is and what it is used for
- 2 Before CERNEVIT is given
- 3 How CERNEVIT is given
- 4 Possible side effects
- 5 How to store CERNEVIT
- 6 Further information

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 sterile solution that contains multi-vitamins.

CERNEVIT is used to give your daily requirement of multi-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 Before CERNEVIT is given

CERNEVIT must not be given if:

- you are allergic (hypersensitive) to any of the ingredients of CERNEVIT (see Section 6)
- 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 apply to you. If you are not sure talk to your doctor, nurse or pharmacist.

**Your doctor will take special care with 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 inflammatory bowel disease (enterocolitis). 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 apply 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).

#### Using other medicines

Please tell your 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.

In particular tell your doctor, nurse or pharmacist if you are taking any of the following medicines. This is because some of the ingredients in CERNEVIT can affect the way some medicines work:

- levodopa (a medicine used for Parkinson's disease). The vitamin B<sub>6</sub> (pyridoxine) in CERNEVIT can affect this medicine
- phenytoin (used for fits or convulsions and sometimes other conditions). The folic acid in CERNEVIT may interact with certain medicines, such as phenytoin.

#### Tests while you are having CERNEVIT

If you are due to have a blood test, tell your doctor you are having CERNEVIT. 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<sub>12</sub> from your gut.

#### Pregnancy and breast-feeding

If you are pregnant, think you might be pregnant or are breast-feeding, tell your doctor. They will decide if you can have CERNEVIT.

### 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 usual 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 usual 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 that you will be given too much. If you are worried that you have had too much, tell your doctor or nurse.

### 4 Possible side effects

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

**Tell your doctor, nurse or pharmacist straight away if you notice any of the following side effects:**

- sneezing or mild asthma. It may be an allergic reaction to vitamin B<sub>1</sub> in CERNEVIT.

Other possible side effects include:

- a rise in the levels of certain liver enzymes, called SGPT transaminases, in people with inflammatory bowel disease (enterocolitis). If you have inflammatory bowel disease your doctor will carefully monitor your levels of these enzymes.

If you notice these or any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

### 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 out of the reach and sight of children.
- CERNEVIT 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 25°C.
- 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.
- 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.