

## **Package leaflet: Information for the user**

### **VitaNor film-coated tablets**

thiamine hydrochloride / pyridoxine hydrochloride / cyanocobalamin

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

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

- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

### **What is in this leaflet**

1. What VitaNor is and what it is used for
2. What you need to know before you take VitaNor
3. How to take VitaNor
4. Possible side effects
5. How to store VitaNor
6. Contents of the pack and other information

#### **1. What VitaNor is and what it is used for**

The active ingredients of VitaNor are the water-soluble vitamins B<sub>1</sub> (thiamine), B<sub>6</sub> (pyridoxine) and B<sub>12</sub> (cyanocobalamin), which are involved in numerous processes of human metabolism.

VitaNor is indicated in the prevention and treatment of vitamin B<sub>1</sub>, B<sub>6</sub> and B<sub>12</sub> deficiency due to increased needs, reduced consumption or absorption, which could present as symptoms of back pain, in convalescence or poor diets.

VitaNor film-coated tablets is indicated in adults and adolescents over 14 years old.

#### **2. What you need to know before you take VitaNor**

##### **Do not take VitaNor**

- If you are allergic to vitamin B<sub>1</sub>, B<sub>6</sub>, or the different forms of vitamin B<sub>12</sub>, to cobalt or any of the other ingredients of this medicine (listed in section 6).
- If you are being treated with L-dopa (a medicine for Parkinson's disease).
- If you suffer from Leber's disease (a hereditary disease causing loss of vision) or tobacco amblyopia (decreased visual acuity, which can occur in people who abuse tobacco), because they could get worse.

Given the doses it contains, do not take this medicine:

- If you suffer from liver or kidney diseases.
- If you are pregnant or breastfeeding.
- Children under 14 years of age.

## **Warnings and precautions**

Talk to your doctor or pharmacist before taking VitaNor.

- You should not take a higher dose than recommended or for a longer period of time than recommended; when applicable, regular monitoring by your doctor is recommended since cases of neuropathies have been observed after the intake of high and continuous daily doses of vitamin B<sub>6</sub>.
- If you suffer from any blood disease, such as anaemia, your doctor should check its cause before taking vitamin B<sub>12</sub>.
- There have been cases of pyridoxine dependence and withdrawal when taking doses of pyridoxine (vitamin B<sub>6</sub>) for a month even lower than that contained in this medicine.
- You should avoid exposure to the sun and ultraviolet rays, due to a possible risk of photosensitivity (with the appearance of skin lesions such as rashes or blisters).
- If you have previously suffered from allergy to vitamin B<sub>1</sub> due to skin contact (contact dermatitis) for professional reasons, you may experience a relapse when taking this medicine.

## **Interference with analytical tests**

If you are going to undergo any diagnostic test (including blood tests, urine tests, skin tests using allergens, etc.), tell your doctor that you are taking this medicine, since it may alter the results. In some determinations of urobilinogen, theophylline, uric acid, or antibodies against intrinsic factor (IF), false results could be produced.

## **Children**

This medicine is contraindicated in children under 14 years old.

## **Other medicines and VitaNor**

Tell your doctor or pharmacist if you are taking, have recently taken or might have to take any other medicines.

This medicine may interfere with the following medicines:

- L-dopa (a medicine used to treat Parkinson's disease).
- Phenobarbital, phenytoin (to treat epilepsy).
- Altretramine and 5-Fluorouracil (for some types of cancers).
- Amiodarone (for the heart).
- Neuromuscular blocking drugs (used in anaesthesia, for surgery).
- Several drugs can interfere with pyridoxine (vitamin B<sub>6</sub>) and can reduce its levels, including: antibiotics to cure tuberculosis (isoniazid, cycloserine, ethionamide, and pyrazinamide), penicillamine (for rheumatic diseases), hydralazine (for blood pressure), immunosuppressants such as corticosteroids, cyclosporine (used in organ transplants, among other diseases).
- Several drugs can decrease the absorption of vitamin B<sub>12</sub> or reduce its effect, such as: ascorbic acid in large doses, antibiotics such as neomycin and chloramphenicol, colchicine (for the treatment of gout), H<sub>2</sub>-antagonists (medicines against heartburn or ulcer of the stomach), amino salicylic acid in long courses (for intestinal diseases), omeprazole (for stomach ulcer), medicines for epilepsy, metformin (for diabetes), folic acid in high doses.
- Oral contraceptives can reduce the levels of vitamins B<sub>6</sub> and B<sub>12</sub>.

## **VitaNor with alcohol**

Excessive alcohol intake reduces the absorption of vitamins.

## **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 using this medicine.

Due to the doses of vitamins B that VitaNor contains, much higher than those recommended during

pregnancy and breast-feeding, this medication is contraindicated during pregnancy and breast-feeding. VitaNor is not recommended in women of childbearing potential not using effective contraception.

### **Driving and using machines**

There are no known effects of the product on the ability to drive or use machines. However, this medication may cause drowsiness in a few patients, who should not drive and/or use dangerous machines during treatment.

### **VitaNor contains Cochineal red (Ponceau 4R) (E-124) and sodium**

This medicine contains Cochineal red (Ponceau 4R) (E-124). It may cause allergic-type reactions.

This medicinal product contains less than 23 mg sodium (1 mmol) per tablet, that is to say essentially 'sodium free'.

### **3. How to take VitaNor**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults and adolescents over 14 years old: 1 tablet daily.

In general, treatment should not exceed 15 days, although your doctor may recommend administration for longer.

If you get worse or if you do not get better after 7 days of treatment, you must talk to your doctor.

For oral administration.

It is preferable that the tablets are swallowed whole with a sufficient amount of water.

#### Patients with renal or hepatic insufficiency

These patients should not take VitaNor (see section 2).

### **If you take more VitaNor than you should**

If you have taken more VitaNor than you should, you may experience symptoms such as: gastrointestinal discomfort (diarrhoea, nausea, vomiting) and headache. Due to the pyridoxine content, you could suffer from nervous disorders such as altered or reduced sensitivity, tingling, numbness in the feet and hands, unstable gait, etc; sensitisation to sunlight with skin rashes may also appear; drowsiness, lethargy, respiratory distress, among other effects, depending on the dose, increased serum concentrations of AST (SGOT) (a transaminase) and decreased serum concentrations of folic acid. In rare cases, a severe allergic reaction (anaphylactic shock) may occur.

In children, accidental ingestion of very high doses of vitamin B<sub>6</sub> can also cause profound sedation, weakness, and respiratory distress.

In the event of an overdose or accidental ingestion, call your doctor or pharmacist immediately, or go to a healthcare centre, specifying the medicine and quantity ingested.

### **If you forget to take VitaNor**

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

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

#### 4. Possible side effects

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

The assessment of the side effects that may occur is based on the following frequencies: very common (may affect more than 1 in 10 people), common (may affect up to 1 in 10 people), uncommon (may affect up to 1 in 100 people), rare (may affect up to 1 in 1,000 people) and very rare (may affect up to 1 in 10,000 people), not known (frequency cannot be estimated from the available data).

Infrequently, nausea, vomiting, headache, drowsiness, paraesthesia (tingling sensation in the arms and legs) and skin rash (redness or swelling) may appear. Hypersensitivity reactions (allergic reactions) to vitamins B<sub>1</sub>, B<sub>6</sub> and B<sub>12</sub> have also been reported.

Other side effects that have been reported, whose frequency is often not exactly known, are: digestive discomfort, diarrhoea, loss of appetite with high doses, photosensitivity with skin lesions such as blisters, redness, itching; very occasionally reduction in the number of platelets (thrombocytopenia); insomnia; disorder with reduced sensation and tingling, among other symptoms, which generally subside when treatment is stopped; worsening of Leber's disease (an inherited disease that causes vision loss); changes in the colour of urine, which usually disappears within 48 hours; occasionally anaphylactic reaction with itching, sweating, shortness of breath, increased heartbeat, etc. Repeated administration of vitamin B<sub>1</sub> may cause relapses of allergic skin reactions in people allergic to this vitamin.

If an allergic reaction occurs, treatment should be stopped, and a doctor should be consulted immediately for appropriate treatment.

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store VitaNor

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

Aluminium//PVC-ACLAR®(PCTFE) blister: Store below 30°C.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 6. Contents of the pack and other information

##### What VitaNor contains

- The active substances are: thiamine hydrochloride (vitamin B<sub>1</sub>), pyridoxine hydrochloride (vitamin B<sub>6</sub>), and cyanocobalamin (vitamin B<sub>12</sub>).  
Each tablet contains 250 mg of thiamine hydrochloride, 250 mg of pyridoxine hydrochloride, and 500 micrograms of cyanocobalamin.
- The other ingredients (excipients) are:  
*Core*: pregelatinised corn starch, anhydrous citric acid, sodium citrate dihydrate, colloidal silica, copovidone, sodium starch glycolate type A (potato), and sodium stearyl fumarate.  
*Coating*: hypromellose, titanium dioxide (E171), glycerol, propylene glycol dicaprylocaprate, Cochineal red (Ponceau 4R) (E124), and carnauba wax.

**What the product looks like and contents of the pack**

This medicinal product is available as pink, elliptical, biconvex, film-coated tablets.  
Package with 30 tablets.

**Marketing authorisation holder and manufacturer**

Laboratorios Normon, S.A.

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