

## **PACKAGE LEAFLET: Information for the patient**

### **VICOM-B**

Solution for injection – (10 mg + 2 mg + 10 mg + 100 mg) / 2 ml

(Thiamine hydrochloride, Riboflavin, Pyridoxine hydrochloride, Nicotinamide)

**Read all of this leaflet carefully before you start taking this medicine 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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

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

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

#### **1. WHAT VICOM-B IS AND WHAT IT IS USED FOR**

Vicom-B contains the active substances thiamine hydrochloride (vitamin B1), riboflavin (vitamin B2), pyridoxine hydrochloride (vitamin B6) and nicotinamide (vitamin B3), which belong to the vitamins of B group. These vitamins are part of the enzymes that catalyze reactions in the metabolism of sugars, fats and proteins. The combination of B group vitamins is used for their effect in a variety of important processes and functions of the body and mainly in the inflammatory and degenerative diseases of the nerves and motor apparatus.

Vicom-B, as a solution for injection, is used to treat conditions of B group vitamin deficiency.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE VICOM-B**

### **Do not take Vicom-B if you:**

- are hypersensitive (allergic) to any of the active substances or to any of the excipients of Vicom-B, since anaphylactic reactions may occur;
- have hypertension of the second or third stage;
- have glaucoma;
- have gout;
- have hypotension;
- have ulcer disease.

### **Take special care with Vicom-B**

Anaphylactic reactions may occur from parenteral use of thiamine (vitamin B1). If Vicom-B is going to be used in a sensitive person, the intradermal testing is advisable.

Long-term use of high doses of pyridoxine is associated with the development of severe peripheral neuropathies; the dose at which these occur is controversial.

High doses of riboflavin may result in a bright yellow discoloration of urine and may interfere with certain laboratory tests.

Special care is recommended in malignant diseases, hepatitis, gastritis.

### **Other medicines and Vicom-B**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Drugs that may interact with Vicom-B are:

- neuromuscular blocking agents: vitamin B1 may enhance the effect of neuromuscular blocking agents;
- adrenolytic and sympatholytic agents: vitamin B1 may decrease the hypotensive effect of some adrenolytic and sympatholytic agents;
- barbiturates and glutethimide: vitamin B1 may decrease the hypnotic effect of barbiturates and glutethimide;
- chlorpromazine: increases urine excretion of vitamin B2;
- probenecid: decreases urine excretion of vitamin B2;

- levodopa: vitamin B6 reduces the effects of levodopa, but this does not occur if a dopa-decarboxylase inhibitor is given concomitantly;
- oral contraceptive agents, hydralazine, isoniazide, penicillamine, cycloserine and thiosemicarbazones: the blood concentration of vitamin B6 decreases;
- phenobarbital and phenytoin: vitamin B6 has been reported to decrease serum concentrations of phenobarbital and phenytoin.

Nicotinamide enhances the anti-hypertensive effects of suppressant drugs of the sympathetic nervous system and is an agonist of isoniazide.

Thiamine appears to be incompatible with the hyposulfate salts and is unstable in neutral or alkaline solutions such as: carbonates, citrates, barbiturates, erythromycin lactobionate IV.

### **Taking Vicom-B with food and drinks**

There is no data on the need for a particular diet or the restriction of certain types of food and drink during the time of treatment with this product.

### **Pregnancy**

Inform your doctor or pharmacist if you are pregnant, think you may be pregnant or are planning to have a baby.

Vitamin B6 passes the placenta, therefore Vicom-B is not recommended to be used during pregnancy.

### **Breastfeeding**

Inform your doctor or pharmacist if you are breast-feeding. Severely thiamine-deficient mothers should avoid breast-feeding as toxic methyl-glyoxal is present in milk. It is not recommended to be used during breast-feeding, only if it is necessary.

### **Driving and using machines**

No studies have been performed on the ability to drive and use machines.

### **3. HOW TO TAKE VICOM-B**

Always take Vicom-B exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dosage is described below:

The solution for injection is administered at a dose of 1-2 ml, every day or every other day. The course of treatment varies from 5 to 10 days.

#### **If you take more Vicom-B than you should**

If you take more Vicom-B than you should or if the children have taken this medicine by mistake, contact your doctor or the nearest hospital or call the emergency service to ask for the risks and advice on the actions that should be taken.

Do not take more Vicom-B than the quantity recommended by your doctor.

In rare cases fatal anaphylactic shock may occur.

Vitamin B<sub>6</sub> is usually not toxic, chronic use of high doses is associated with neurological side effects.

#### **If you forget to take Vicom-B**

If you forget to take one dose (ore more), take the next dose in its usual time. Do not take a double dose (or more) to make up a forgotten dose (doses).

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

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Vicom-B can cause side effects, although not everybody gets them.

Vicom-B is very well tolerated, however, in rare cases, itching, urticaria, and Quincke's edema may be observed in predisposed patients.

Adverse effects of thiamine are rare, but hypersensitivity reactions have occurred, up to fatal anaphylactic shock.

Long-term use of high doses of vitamin B<sub>6</sub> is associated with the development of severe peripheral neuropathies; the dose at which these occur is controversial.

High doses of riboflavin result in a bright yellow discoloration of urine and may interfere with certain laboratory tests.

If any of the side effects gets worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **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. You can also report side effects to the Pharmacovigilance Department of the National Agency of Drugs and Medical Devices at the email address [farmakovigjilenca@akbpm.gov.al](mailto:farmakovigjilenca@akbpm.gov.al) or via the website [www.akbpm.gov.al/formulari-raportimi](http://www.akbpm.gov.al/formulari-raportimi). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE VICOM-B**

Keep out of the sight and reach of children!

Do not use Vicom-B after the expiry date which is stated on the package!

Do not store above 25°C!

Keep in the original package to protect it from light.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Vicom-B solution for injection contains**

**The active substances are:** thiamine hydrochloride (vitamin B1), riboflavin (vitamin B2), pyridoxine hydrochloride (vitamin B6) and nicotinamide (vitamin B3).

Each ampoule of 2 ml contains 10 mg thiamine hydrochloride, 2 mg riboflavin (as riboflavin sodium phosphate), 10 mg pyridoxine hydrochloride and 100 mg nicotinamide.

**The excipients are:** sodium bicarbonate, disodium-EDTA, polysorbate 80, hydrochloric acid or sodium hydroxide, water for injection.

### **Contents of the Pack**

Carton box with 10 ampoules of 2 ml.

**Marketing Authorisation Holder (MAH) and Manufacturer**

Profarma sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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