

PACKAGE LEAFLET: Information for the patient

VITAMINA B1

Tablets – 10 mg

Solution for injection – 50 mg / 1 ml

(Thiamine hydrochloride)

Read all of this leaflet carefully before you start taking this medicine.

- 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. 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 becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Vitamina B1 is and what it is used for
2. Before you take Vitamina B1
3. How to take Vitamina B1
4. Possible side effects
5. How to store Vitamina B1
6. Further information

1. WHAT VITAMINA B1 IS AND WHAT IT IS USED FOR

Vitamina B1 (thiamine hydrochloride) belongs to the group of water-soluble vitamins, although some of its derivatives have greater lipophilicity.

The main functions of thiamine hydrochloride are: carbohydrate metabolism, normal development of organism, neural impulse conductor and acetylcholine synthesis. Thiamine is essential for the normal aerobic metabolism. It combines with adenosine triphosphate (ATP) in the presence of thiamine diphosphokinase, to form thiamine pyrophosphate, an important coenzyme which is also known as cocarboxylase.

Thiamine pyrophosphate is the active form of thiamine which acts as a coenzyme in carbohydrate metabolism (in the decarboxylation of α -keto acids such as pyruvic acid and of α -ketoglutarate).

Thiamine deficiency appears when its intake with food is inadequate.

Severe deficiency causes beri-beri disease which is characterised by gastrointestinal disorders and peripheral neuropathy.

Vitamina B1 tablets and solution for injection are used in the following clinical situations:

- prophylaxis or treatment of thiamine deficiency (beri-beri);
- prophylaxis of Wernicke-Korsakoff syndrome;
- treatment of ulcerative colitis, chronic diarrhea, cerebellar syndrome, polyneuritis and as appetite stimulant.

Administration of solution of injection is indicated when the oral administration is not possible or not recommended.

2. BEFORE YOU TAKE VITAMINA B1

Do not take Vitamina B1 if you are hypersensitive to thiamine hydrochloride or to any of the excipients of the tablet or solution for injection.

Take special care with Vitamina B1

Caution should be taken in case of hypersensitivity reactions. When Vitamina B1 is taken in the form of tablets, this phenomenon is rare, while when taken parenterally (intramuscular or intravenous) it is advised to perform intradermal test. Fatal cases have been reported from the intravenous injection of the solution for injection of vitamin B1.

Taking other medicines

Concomitant treatment with other drugs, may affect or be affected by Vitamina B1. Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those without a prescription. Remember to inform your doctor if you are given another drug during treatment.

It is important to inform your doctor if you are taking:

- neuromuscular blocking agents because vitamin B1 can increase their effect. The clinical importance of this remains unknown;
- antacids because they inhibit the absorption of vitamin B1.

Taking Vitamina B1 with food or drinks

The rate of absorption of Vitamina B1 tablets is affected by the concomitant intake of food.

Pregnancy

Category C.

If you are pregnant, ask your doctor for advice before taking this drug.

It is not recommended to use Vitamina B1 during pregnancy at doses higher than those recommended to be taken through diet, unless the benefit exceeds the potential risk.

During pregnancy, the needs for vitamin B1 are increased, but despite this, the amount received with the diet is usually sufficient.

Breastfeeding

Vitamin B1 (thiamine hydrochloride) concentration in breast milk does not affect significantly the child. It is thought that its use is compatible with breastfeeding.

Driving and using machines

There is no evidence that vitamin B1 affects the ability to drive or use machines.

Important information about some of the excipients of Vitamina B1 tablets

Vitamina B1 tablets contain lactose. If you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE VITAMINA B1

Always take Vitamina B1 tablets or solution for injection exactly as your doctor has told you. If you feel that the effect of Vitamina B1 is too strong or too weak, talk to your doctor or pharmacist.

The tablets are for oral administration

Adults: 10-20 mg, 1-2 times / day.

Children up to 1 year: 5 mg / day.

Children 2-6 years: 10 mg / day.

Children 7-12 years: 20 mg / day.

The solution for injection is for subcutaneous, intramuscular, intravenous administration

Adults: 50 - 100 mg / day.

Children up to 1 year: 2.5 - 5 mg / day.

Children 2-6 years: 5 - 10 mg / day.

Children 7-12 years: 12.5 - 25 mg / day.

Intravenous use is reserved for very rare cases and should be by infusion over 30 minutes.

If you take more Vitamina B1 than you should

If you take more Vitamina B1 than you should, or if the children have been taking this medicine by accident, please contact your doctor, the hospital or call the emergency to get an opinion of the risk and advice on the actions to be taken.

If you forget to take Vitamina B1

If you forget a dose, take the next dose when it is the normal time to take it.

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Vitamina B1 can cause side effects, although not everybody gets them. Sometimes they may be serious, sometimes not. Do not panic from this list of possible side effects. You may not get any of them.

Sometimes nausea, hemorrhage in digestive tract, pulmonary edema, cyanosis, angioneurotic edema, pruritus, urticaria, feelings of warmth, sweating, weakness, hypotension and cardiovascular collapse have been reported. These symptoms disappear with dose reduction or interruption of treatment with vitamin B1.

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

5. HOW TO STORE VITAMINA B1

Keep out of the reach and sight of children.

Do not use Vitamina B1 after the expiry date which is stated on the package.

Do not store above 25°C.

Store in the original package to protect it from light.

6. FURTHER INFORMATION

The active substance is thiamine hydrochloride.

What Vitamina B1 tablets contain

Each tablet contains 10 mg thiamine hydrochloride.

The excipients are: lactose, microcrystalline cellulose, tartaric acid, talc, magnesium stearate, sodium starch glycolate.

What Vitamina B1 solution for injection contains

Each ampoule 1 ml contains 50 mg thiamine hydrochloride.

The excipients are: sodium dihydrogenphosphate dihydrate, disodium hydrogen phosphate dihydrate, hydrochloric acid may be added for pH adjustment, thiourea, water for injection.

Contents of the pack

Tablets: carton with 30 tablets and carton with 60 tablets.

Solution for injection: box with 10 ampoules.

Marketing authorisation holder and manufacturer:

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Tirana, Albania.

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This leaflet was last revised in November 2023.