

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Shalosh B Tablets

Composition:

Each tablet contains:

Thiamine hydrochloride (vitamin B1)

100 mg

Pyridoxine hydrochloride (vitamin B6)

250 mg

Cyanocobalamin (vitamin B12) 0.25 mg

For the list of inactive ingredients see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

The medicine is intended as a supplement of vitamins from the B group.

For the treatment of neurological pain and metabolic disorders according to the doctor's recommendation.

Therapeutic class: a combination of vitamins from the B group (B1, B6, B12).

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredients or to any of the other ingredients this medicine contains (see section 6 – "Additional information").
- You have Leber's disease (hereditary optic nerve atrophy which causes loss of vision).

Special warnings regarding the use of the medicine

Before treatment with Shalosh B, inform the doctor if:

- You are about to undergo any medical or diagnostic tests (including blood tests, urine tests, skin tests with allergens, etc.). This medicine can change the test results. In some tests of bilirubin, theophylline, uric acid or intrinsic factor (IF) antibodies, false results may be obtained.
- You suffer from a blood disease, such as anemia. The doctor will check the reason for this before giving vitamin B12.
- You have suffered in the past from allergy to vitamin B1 due to contact with the skin during work (occupational contact dermatitis) – the problem may recur when taking this medicine.

Additional warnings

- Taking an excessive dosage may cause damage to the nervous system.
- Do not use this medicine in a dosage higher than recommended or often. Routine follow-up by the doctor is recommended following a report of damage to the nervous system after taking a high daily dosage of vitamin B6 for a prolonged time.
- Cases of vitamin B6 (pyridoxine) dependence and withdrawal effects have been reported after taking vitamin B6 for a month, even at a lower dosage than that contained in this medicine.
- A possible side effect of vitamin B6 (pyridoxine) is peripheral neuropathy, characterized by symptoms such as numbness, tingling and burning sensation, usually in the hands and feet. There is an increased risk for this side effect when using high doses or following prolonged treatment with preparations containing vitamin B6. If you experience symptoms such as: numbness, tingling or burning sensation, you should stop the treatment and contact the doctor.

Children and adolescents
The medicine is not intended for children under the age of 6 years.

Drug interactions
If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor

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If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor

or the pharmacist. Especially if you are taking:

- Phenobarbital, phenytoin (for the treatment of epilepsy)
 - al tretamine and 5-fluorouracil (for certain types of cancer)
 - Amiodarone (for treatment of the heart)
 - Medicines that block neuromuscular activity (used for anesthesia in surgery)
- Several medicines can interfere with the absorption of vitamin B6 and reduce its concentration, including:
- Antibiotics for the treatment of tuberculosis (isoniazid, cycloserine, ethionamide and pyrazinamide)
 - Penicillamine (for rheumatic diseases)
 - Hydralazine (for treatment of blood pressure)
 - Immunosuppressive agents such as corticosteroids
 - Cyclosporine (used in organ transplantation as well as other diseases)

Several medicines can reduce the absorption of vitamin B12 or reduce its activity, such as:

- Ascorbic acid (vitamin C) in high doses
- Antibiotics such as neomycin and chloramphenicol
- Colchicine (for treatment of gout)
- H2 antagonists (medicines for treatment of heartburn or stomach ulcer)
- Aminosalicylic acid for long periods (for bowel diseases)
- Omeprazole (for stomach ulcer)
- Anti-epileptic medicines
- Metformin (for diabetes)
- Folic acid in high doses
- Contraceptive pills may reduce the concentration of vitamin B6 and B12
- Levodopa (for Parkinson's disease)

Use of the medicine and food

The medicine should be swallowed with a glass of water. May be taken with or without food.

Use of the medicine and alcohol consumption

Excessive drinking of alcohol impairs the absorption of vitamins.

Pregnancy, breastfeeding and fertility
If you are pregnant, planning to become pregnant or breastfeeding, consult the doctor before taking the medicine.

The medicine is not recommended for use in women of childbearing age who are not using effective contraceptives.

Driving and operating machinery

There is no information about known effects of the medicine that affect the ability to drive or operate machinery. Nevertheless, this medicine may cause drowsiness in a number of patients, and they should not drive or use dangerous machinery during treatment.

Important information about some of the ingredients of the medicine

This medicine contains less than 23 mg of sodium per tablet, and is therefore considered sodium-free.

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation. The dosage and treatment regimen will be determined by the doctor only. The generally accepted dosage is: 1-2 tablets per day.

Do not exceed the recommended dose.

Method of use

The medicine should be swallowed with some water.

Crushing/halving/chewing

In cases of difficulty swallowing, the tablet can be crushed/pulverized and swallowed immediately. In the absence of a score line, do not halve the tablet.

If you have taken a higher dosage

If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting without an explicit instruction from the doctor.

When taking an overdose, you may feel the following symptoms:

Discomfort in the digestive system (diarrhea, nausea, vomiting).

Due to the pyridoxine (vitamin B6) content in the medicine, there may be effects in the nervous system, such as: altered or reduced sensitivity, tingling, lack of sensation in the legs or hands, unsteady walking etc. There may be sensitivity to

sunlight with skin rash, drowsiness, coma, respiratory distress and other effects which are dose-dependent, increased transaminase AST (SGOT) levels in the blood and reduction in the concentration of folic acid in the blood.

In rare cases, there may be a severe allergic reaction (anaphylactic shock).

Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

As with any medicine, using Shalosh B may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

You should stop using the medicine and immediately refer to the doctor or to a nearby hospital emergency room in the following case: irritation or skin rash occurs.

You should stop the treatment and refer to the doctor in the following case: You experience symptoms such as: numbness, tingling or burning sensation (peripheral neuropathy).

Uncommon side effects – effects that occur in 1-10 users out of 1,000:

Nausea, vomiting, headache, drowsiness, tingling sensation in the hands and legs and skin rash (redness or swelling). Hypersensitivity reactions (an allergic reaction) to vitamin B1, B6, B12 have been reported.

Side effects with unknown frequency (effects whose frequency has not yet been determined):

- Digestive discomfort
- Diarrhea
- Loss of appetite in high doses
- Sensitivity to light with skin ulcers such as blisters, redness, itching

- Infrequently, decrease in platelet count, sleeplessness
 - Decreased sensation and tingling
- Additional effects which usually stop when treatment is stopped:

- Worsening of Leber's disease (hereditary optic nerve atrophy which causes loss of vision)
- Changes in the color of urine, which usually disappear after 48 hours
- Occasionally anaphylactic (allergic) reaction with itching, sweating, shortness of breath, increased heart rate, etc.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning.
- Do not use the medicine after the expiry date (EXP) appearing on the package. The expiry date refers to the last day of that month.
- Storage conditions:** store in the original package at a temperature lower than 25°C.

6. Additional information

In addition to the active ingredients the medicine also contains:

Microcrystalline Cellulose (MCC), Maltodextrin, Povidone K-25, Opadry White (Hypromellose, Titanium Dioxide, Macrogol), Magnesium Stearate, Sodium Citrate Dihydrate, Citric Acid, FD&C Red No. 40.

What does the medicine look like and what are the contents of the package?
Shalosh B tablets are round, film coated, biconvex and pink in color. The tablets are

packed in trays in packages of 10, 20, 30, 50, 60, 90 tablets. Not all package sizes may be marketed.

Registration number of the medicine in the national drug registry of the Ministry of Health:
144-02-31942-00

Manufacturer and license holder: CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi, 8305769.

This leaflet was revised in August 2025 in accordance with the Ministry of Health guidelines.

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