

**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 your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

The medicine is not intended for children under the age of 6 years old.

Consult the pharmacist if you need more information.

1. What is the medicine intended for?

The medicine is intended as a vitamin supplement 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).



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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 atrophy of the optic nerve).

Special warnings regarding the use of the medicine

- Do not use this medicine frequently or for a prolonged period of time without consulting the doctor.
- If you are sensitive to any type of food or medicine, inform your doctor before starting treatment with this medicine.
- Taking an excessive dosage may cause damages to the nervous system.
- **Before treatment with the medicine tell the doctor if you are pregnant or breastfeeding.**
- Peripheral neuropathy may occur following high dosage use and/or prolonged use of preparations containing vitamin B₆. Stop taking the preparation if symptoms such as numbness, tingling and a burning sensation appear, usually in the hands and feet, which can indicate neuropathy, and consult the treating doctor as soon as possible.

Drug interactions

If you are taking or have recently taken other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. In particular, tell the doctor or pharmacist if you are taking:

- Levodopa (for Parkinson's disease).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, consult the doctor before taking this medicine.

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 the method of treatment.

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 administration – The tablet 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.

Follow the treatment as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose every time you take the 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.

Discontinue use of the medicine and refer to a doctor immediately if irritation or rash appears on the skin.

If a side effect occurs, or 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 below 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 marketing authorization holder: CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi, 8305769. This leaflet was revised in October 2021 in accordance with the Ministry of Health guidelines.