Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Tribemin Tablets

Active ingredient
Each tablet contains:

Thiamine HCl (vitamin B1) 100 mg
Pyridoxine HCl (vitamin B6) 250 mg
Cyanocobalamin (vitamin B12) 0.25 mg

Inactive ingredients and allergens in the medicine - see section 6 'Additional information'.
Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat 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 to yours.

1. What is this medicine intended for?

- The medicine is intended as a B group vitamin supplement
- For the treatment of neurologic pain and metabolic disorders

Therapeutic group: A combination of B group vitamins (B1, B6, B12)

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).
- You suffer from Leber's disease (hereditary optic nerve atrophy causing vision loss).

Special warnings about using this medicine
Before treatment with Tribemin, tell your doctor if:

- You are about to undergo any tests – medical or diagnostic tests (including blood, urine tests, skin tests with allergens, etc.). This medicine can change the test results. Erroneous results may be obtained in some tests for bilirubin, theophylline, uric acid or intrinsic factor (IF) antibodies.
- You have a blood disease such as anemia; your doctor will examine the reason for this before administering vitamin B12.
- You have previously had occupational contact dermatitis due to allergy to vitamin B1; this problem may recur upon taking this medicine.

Additional warnings

- Use of an excessive dose may cause damage to the nervous system.
- Do not use this medicine at a dose higher than recommended or frequently. Routine doctor's follow-up is recommended in view of reports on damage to the nervous system after prolonged intake of high daily dose of vitamin B6.
- Cases of vitamin B6 (pyridoxine) dependence and withdrawal symptoms have been reported upon vitamin B6 intake for one month, even at a dose lower than its content in this medicine.

- A possible side effect of vitamin B6 (pyridoxine) is peripheral neuropathy, characterized by symptoms such as paresthesia, tingling and burning sensation, usually in the hands and feet. There is a higher risk of this side effect upon high dose use or after prolonged treatment with medicines containing vitamin B6. If you experience symptoms such as paresthesia, tingling and burning sensation, stop the treatment and contact your doctor.

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

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:
phenobarbital, phenytoin (for treatment of epilepsy)
altretamine and 5-fluorouracil (for certain cancer types)
amiodarone (for heart treatment)
neuromuscular blocking agents (used for anesthesia in surgery)

Some medicines may interfere with the absorption of vitamin B6 and reduce its concentration, including:
antibiotics for treatment of tuberculosis (isoniazid, cycloserine, ethionamide and pyrazinamide)
penicillamine (for rheumatic diseases)
hydralazine (for blood pressure lowering)
immunosuppressants such as corticosteroids
cyclosporine (used in organ transplantation in addition to other diseases)

Some medicines may reduce the absorption of vitamin B12 or reduce its activity, such as:
ascorbic acid (vitamin C) at high doses
antibiotics such as neomycin and chloramphenicol
colchicine (for treatment of gout)
H3 antagonists (medicines for treatment of heartburn or gastric ulcer)
aminosalicylic acid for long periods (for bowel diseases)
omeprazole (for gastric ulcer)
medicines for epilepsy
metformin (for diabetes)
folic acid at high doses
Contraceptive pills may reduce the concentration of vitamins B6 and B12.
levodopa (for Parkinson).

Using this medicine and food
Swallow the medicine with a glass of water. Can be taken with or without food.

Using this medicine and alcohol consumption
Increased alcohol consumption impairs vitamin absorption.

Pregnancy and breastfeeding
If you are pregnant, planning to become pregnant or breastfeeding, consult your doctor prior to taking the medicine.
The medicine is not recommended for women of childbearing age who are not using effective contraceptive methods.

Driving and using machines

There is no information about known effects of the medicine influencing the ability to drive or operate machines. However, this medicine may cause somnolence in some patients, who must not drive or use dangerous machines during the treatment.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.
The recommended dosage is usually 1-2 tablets per day.

Do not exceed the recommended dose.

Method of administration
Swallow the medicine with some water.
If necessary, you can crush the tablets and swallow immediately.
If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.
If you take an overdose, you may experience the following symptoms:
Gastrointestinal discomfort (diarrhea, nausea, vomiting).
Due to the pyridoxine content in the medicine, nervous system effects may occur, such as altered or reduced sensitivity, tingling, numbness in the legs or arms, unstable gait, etc. There may be sensitivity to sunlight with skin rash, somnolence, coma, respiratory distress, as well as other dose-dependent effects, increased blood levels of the transaminase AST (SGOT) and decreased blood concentration of folic acid.
In rare cases, a severe allergic reaction (anaphylactic shock) may occur.

Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor or pharmacist.

Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Tribemin may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop using the medicine and contact your doctor immediately or go to the nearest hospital emergency room in the following case:
Appearance of skin irritation or rash.

Stop the treatment and contact your doctor in the following case:
You experience symptoms such as paresthesia, tingling or burning sensation (peripheral neuropathy).

Uncommon side effects - affect 1-10 in 1,000 users
Nausea, vomiting, headache, somnolence, tingling sensation in the arms and legs and skin rash (redness or swelling).
Hypersensitivity reactions (allergic reaction) to vitamins B1, B6, B12 have been reported.

Side effects of unknown frequency (the frequency of these effects has not been established yet)

- Dyspepsia,
- Diarrhea,
- Loss of appetite at high dose,
- Sensitivity to light with skin ulcers such as blisters, redness, itching,
- Rarely decreased platelet number, insomnia,
- Effect of reduced sensation and tingling,

In addition to other effects, which usually resolve upon treatment discontinuation,

- Worsening of Leber's disease (hereditary optic nerve atrophy causing vision loss),
- Urine discoloration, which usually resolves after 48 hours,
- Occasionally anaphylactic (allergic) reaction with itching, sweating, shortness of breath, increased heart rate, etc.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

- Store at a temperature below 25˚C (room temperature).
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
microcrystalline cellulose, povidone 30, eudragit L 12.5%, titanium dioxide, magnesium stearate, colloidal silicon dioxide, dibutyl sebacate, polysorbate 80, carbowax 6000, Red Lake No 3.

What the medicine looks like and contents of the pack:
A blister pack containing pink tablets.
Each pack contains 10, 20, 30 or 90 tablets.
Not all pack sizes may be marketed.

Manufacturer's and Registration Holder's name and address: Sam-On Ltd., 25 Ehud Kinamon (Ha'avoda) St., Bat Yam.

Revised in December 2024.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
040-39-22836-00