PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed without a doctor's prescription

TRIBEMIN

Composition:

Each tablet contains: Thiamine HCI (Vitamin B₁) 100 mg

Pyridoxine HCl (Vitamin B₆) 250 mg Cyanocobalamine (Vitamin B₁₂) 250 mcg

Inactive ingredients - see section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor of pharmacist.

The medicine is not intended for children below 6 years of age. You must swallow it in the correct manner. Consult the pharmacist if you need further information.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended as a B group vitamin supplement.
For the treatment of neurologic pain and metabolic disorders according to the doctor's recommendation.

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

2. BEFORE USING THE MEDICINE

Do not use this medicine if:
There is a known sensitivity to any of the medicine's ingredients.
You are suffering from Leber's disease (hereditary optic nerve atrophy).

- Special warnings regarding use of this medicine

 Do not use this medicine frequently or for a prolonged period without consulting a doctor.

- a doctor.
 If you are sensitive to any kind of food or medicine, inform the doctor before taking the medicine.
 Use of an excessive dose may cause harm to the nervous system.
 Before commencing treatment with Tribemin inform the doctor if you are pregnant or breastfeeding.

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

• levodopa (for Parkinson's).

■ Pregnancy and breastfeeding:
If you are pregnant or breastfeeding consult the doctor before taking the medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain. The usual dosage is generally: 1-2 tablets per day. Do not exceed the recommended dose.

Method of administration - Swallow the medicine with water.

If necessary it is permissible to crush the tablets and then swallow the tablets immediately.

immediately. If you took an overdose or if a child accidentally swallowed the medicine, refer immediately to a doctor or a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting unless explicitly instructed to do so by the doctor.

so 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 each time you take the medicine. Wear glasses if you need them.

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

4. SIDE EFFECTS

As with any medicine, use of Tribemin 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.

Stop treatment and refer immediately to the doctor in case of skin irritation or eruption. If one of the side effects worsens, or if you experience side effects that are not mentioned in the leaflet, consult with the doctor.

Reporting side effects

neporting side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

5. HOW SHOULD THE MEDICINE BE STORED?

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 Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning.
 Do not use the medicine after the expiry date (exp. date) appearing 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).

6. FURTHER INFORMATION

- Manufacturer and registration holder and address: Sam-On Ltd., 25 Ha'avoda
- This leaflet was checked and approved by the Ministry of Health in August



https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=Advers EffectMedic@moh.gov.il

- In addition to the active ingredients the medicine also contains:

 Povidone, Microcrystalline Cellulose, Magnesium Stearate, Colloidal Silicon
 Dioxide, Eudragit L, Titanium Dioxide, Red Lake No. 3, Polyethylene Glycol
 6000, Polysorbate 80, Dibutyl Sebacate

 What the medicine looks like and the contents of the package blister package
 containing pink tablets.

 Manufacturer and registration bolder and editors in Control States.

- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 40-39-22836