

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

The medicine is dispensed without
a doctor's prescription

Calmanervin Tablets

101080086/04

- The active ingredient and its quantity:
 - Each tablet contains:
 - Passiflora Dry Extract 250 mg
 - Valerian Dry Extract 60 mg
 - Vitamin B₁ 10 mg
 - Vitamin B₆ 10 mg
- For the list of inactive ingredients, please 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 or pharmacist.

- The medicine is not intended for children under 12 years of age.
- Swallow the medicine properly. Consult a pharmacist if you need further information.

1. WHAT IS THE MEDICINE INTENDED FOR?

- Sedative in states of tension and over-nervousness.
- Hypnotic.

Therapeutic group: Sedatives, hypnotics.

2. BEFORE USING THE MEDICINE:

- Do not use the medicine if:**
- you are sensitive (allergic) to the active ingredients (passiflora, valerian, vitamin B₁ or vitamin B₆) or to any of the other ingredients in the medicine.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist. It is particularly important to inform the doctor or pharmacist if you are taking:

- Hypnotics.
- Sedatives.
- Antiepileptics.
- Levodopa (to treat Parkinson's disease).
- Medicines for anxiety.
- Narcotic analgesics.
- Additional sedatives.
- Alcohol.
- Loperamide.
- Lorazepam.
- Medicines that cause hepatic toxicity.

Use of the medicine and consumption of alcohol:

Do not drink wine and/or alcoholic beverages during the course of treatment with this medicine.

Pregnancy and breastfeeding:

Consult the doctor or pharmacist before taking the medicine if you are pregnant or breastfeeding.

Driving and use of machines:

Use of this medicine may impair alertness and therefore requires that caution be exercised when driving a car, operating dangerous machinery and when engaging in any activity that requires alertness.

3. HOW SHOULD YOU USE THE MEDICINE?

- Check with the doctor or pharmacist if you are uncertain.

The usual dosage is generally:

- As a sedative: 1 tablet, 3-4 times a day.
As a hypnotic: 2 tablets, about half an hour before bedtime.
- The medicine is not intended for children under 12 years of age.

Do not exceed the recommended dose.

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

- Swallow the medicine with water.
- The tablets can be crushed immediately before swallowing.
- Do not store crushed tablets.

If you accidentally took a higher dosage,

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

- Do not take medicines in the dark! Check the label and dose each time you take 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 Calmanervin Tablets may cause side effects in some users, such as: nausea, headache, anxiety and hepatic toxicity in users using it for a prolonged period.

In the event that you experience side effects not listed in this leaflet, or if there is a change in your general health, consult the doctor immediately.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe 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. date) that appears on the package. The expiry date refers to the last day of that month.

- Store, tightly closed, at a temperature that does not exceed 25°C.

- Do not discard medicines in the waste water or waste bin. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION:

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

Microcrystalline Cellulose, Sodium Starch Glycolate, Magnesium Stearate, Colloidal Silicon Dioxide, Pigment Blend, Vanillin, Talc, Eudragit, Titanium Dioxide, Carbowax 6000.

Each tablet contains approximately 0.5 mg sodium.

What the medicine looks like and the contents of the pack: brown, film-coated tablets.

10, 30 tablets in a blister package; 20 tablets in a bottled package.

Manufacturer and license holder: Sam-On Ltd., 25 Haavoda St., Bat-Yam.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
46 30 22917

This leaflet was checked and approved by the Ministry of Health in June 2014.