

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

The medicine is dispensed without a doctor's prescription

CALMANERVIN-S Elixir

The active ingredients and their quantity:

Each teaspoon (5 ml) contains:

Passiflora Liquid Extract 250 mg

Valerian Liquid Extract 60 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 or valerian) or to any of the other ingredients of 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.
- 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.

Important information about some of the ingredients in the medicine:

The medicine contains sugar. If you have been told in the past by your doctor that you have an intolerance to some sugars, consult the doctor before commencing treatment with this medicine.

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 teaspoonful of the Elixir (5 ml), 3-4 times a day.

As a hypnotic: 1-2 teaspoonsful of the Elixir (5-10 ml), 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.

- Shake before use.
- Can be used for 12 months after opening.

Instructions for use of the preparation - general instructions:

1. With liquid medications, you must use a measuring spoon, measuring cup, syringe or dropper meant for measuring the correct amount of the medicine. If a spoon or another measuring device was not attached to the package, consult the pharmacist. Do not use a household spoon to measure the amount of the medicine. Household spoons differ in size and you may not receive the correct amount of medicine.
2. Child-resistant caps have significantly reduced the number of cases of medicine-induced poisoning each year. However, if you find it difficult to open the container, you can ask the pharmacist to remove the safety mechanism in the cap and make it into a regular easy-to-open cap.

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-S Elixir 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 wastewater 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:

Alcohol, Methyl Hydroxybenzoate, Anise Flavour, Sugar, Purified Water.

The preparation contains sugar. Each teaspoon (5 ml) contains 2.5 g sugar.

What the medicine looks like and the contents of the pack: A plastic bottle that contains 120 ml Elixir.

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: 35 48 25445

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