

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

This medicine is dispensed without a doctor's prescription

Songha[®] Night

Coated tablets

Composition:

Active ingredients and their quantity:

Each coated tablet contains:

Dry extract of Valerian root 120 mg

Dry extract of Melissa leaf 80 mg

Inactive ingredients and allergens: See section 6 'Additional information' and section 2 'Important information about some of this medicine's ingredients'.

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.

Use this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information. Consult your doctor if your symptoms of illness get worse or do not improve within 2 weeks.

1. What is this medicine intended for?

The medicine relieves tension and irritability, induces sleep in conditions of difficulties falling asleep.

Therapeutic group:

Extracts of Valerian root and Melissa leaves acting as mild tranquilizers.

2. Before using this medicine

.X. Do not use this medicine if:

You are sensitive (allergic) to the active ingredients or to any of the other ingredients in this medicine.

! Special warnings about using this medicine

Children and adolescents

Due to lack of sufficient clinical data, do not use this medicine in children below the age of 12.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Do not take additional sleep medicines or tranquilizers together with Songha Night without consulting the doctor.

If you visit a doctor or another healthcare professional, remember to tell him that you are taking or have recently taken this medicine.

Using this medicine and food

The medicine can be taken with or without food.

Pregnancy and breastfeeding

Use of Songha Night during pregnancy or breastfeeding is not recommended.

Driving and using machines

Using Songha Night may impair your ability to drive or operate machines.

If you feel that you are affected by Songha Night, do not drive or operate machines. Caution children against riding a bicycle, playing near a road, and similar activities.

Important information about some of this medicine's ingredients

Each tablet contains 31.7 mg glucose and 111.41 mg sucrose.

If you have been told by a doctor that you have an intolerance to certain sugars, consult your doctor prior to using this medicine.

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The recommended dosage is usually:

Adults and children above the age of 12 years:

As sleep inducer:

One dose of 2-3 tablets about half an hour before bedtime.

As a tranquilizer in conditions of tension and irritability:

2-3 tablets 3 times per day.

Swallow the tablets whole.

Consult your doctor if your symptoms do not resolve, or even worsen after 2 weeks of treatment.

Dosage for children

Due to lack of sufficient clinical data, do not use this medicine in children below the age of 12.

Do not exceed the recommended dose.

Swallow the medicine with a small amount of water.

Do not chew the tablet.

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 forget to take Songha Night, do not take a double dose to compensate for the forgotten dose.

Do not take medicines in the dark! Check the label and dose every time you take 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 Songha Night may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Gastrointestinal side effects, such as nausea and abdominal pain (occurred in an unknown number of patients), have been reported after swallowing medicines containing Valerian.

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

Even if stored under the recommended storage conditions, medicines can be kept only for a limited period. Please pay attention to the expiry date of the medicine! In case of any doubt, consult the pharmacist who supplied the medicine to you.

Store below 25°C.

6. Additional information

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

Tablet core:

Microcrystalline cellulose, Colloidal anhydrous silica, Glucose liquid spray-dried, Sodium Starch glycolate Type A, Magnesium stearate.

Tablet coating:

Sucrose, Talc, Spray-dried acacia, Titanium dioxide, Macrogol 6000, Carnauba wax, Indigo carmine.

What the medicine looks like and contents of the pack:

A round, shiny, blue – greyish tablet.

The pack contains 30 sugar coated tablets in a blister.

Manufacturer's name and address:

Soho Flordis International Switzerland SA Via Mulini, 6934 Bioggio, Switzerland

Registration holder's name and address:

Pharmashalom Ltd., 21 Hamelacha St., Industrial Zone, Rosh Ha'Ayin.

This leaflet was revised in June 2021 according to Ministry of Health guidelines

Registration number of the medicine in the Ministry of Health's National Drug Registry:
134-16-29935