1. NAME OF THE MEDICINAL PRODUCT

Songha Night, coated tablets

2. ACTIVE INGREDIENTS

1 tablet contains:
120 mg dry extract of *Valeriana* root and 80 mg dry extract of *Melissa officinalis* leaves

Excipients: sucrose 111.4 mg, liquid spray-dried glucose 31.7 mg.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Coated tablet.
Grey-blue, sugarcoated, biconvex tablet with a diameter of 10 mm.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Sedative in states of tension, nervousness and insomnia

4.2 Posology and mode of administration

Oral use.

Dosage for adults, elderly and adolescence above 12 years:

Insomnia:
2-3 tablets ½ hour before bedtime.
Sedative in states of tension, nervousness:
2-3 tablets, three times a day
Consult with a doctor if symptoms persist or are aggravated after 2 weeks of treatment.

Due to insufficient data, Songha Night should not be used with children below 12 years of age).

4.3 Contraindications

Known hypersensitivity to valerian or melissa or to any excipient of the product listed in section 6.1.

4.4 Special warnings and special precautions for use

The product contains sucrose and glucose. Patients with any of the following rare hereditary conditions should therefore not use this medical product; fructose intolerance, glucose- or galactose malabsorption or sucrose-isomaltase deficiency.

Due to insufficient data, Songha Night should not be used with children below 12 years of age

4.5 Interaction with other medicinal products and other forms of interaction

Valerian: Only limited data on pharmacological interaction with other medical products are available. Clinically relevant data with medical products metabolized by CYP 2D6, CYP 3A4/5, CYP 1A2 or CYP 2E1 has not been observed. Combination of synthetically sleeping medicines or tranquilizers requires a medical diagnosis and supervision.

Melissa : Presently there are no known data on interactions.

4.6 Fertility, pregnancy and lactation

Due to lack of sufficient data, the use during pregnancy and lactation cannot be recommended.
The eventual effect of the medical product on fertility has not been studied.

4.7 Traffic warning

Songha Night have moderate impact on the ability to drive and use machinery. Patients who feel influenced by Songha Night should not drive nor use machines.

4.8 Undesirable effects

Gastrointestinal symptoms (i.e. nausea, abdominal pain) may occur after intake of products containing valerian root. The frequency is unknown.

Reporting suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il

4.9 Overdose

Valerian root: a dose of approximate 20 g valerian root caused benign symptoms (fatigue, abdominal cramps, chest tightness, dizziness, tremor of hands and mydriasis), symptoms which resolved within 24 hours.
Melissa leaf: No cases of overdose have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacoterapeutic group: Sleeping medicines and sedatives, combinations excluding barbiturate, ATC code N05CX.

5.2 Pharmacokinetic properties

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5.3 Preclinical safety data

No mutagenic potential could be indicated in product specific Ames test on the extracts present in Songha Night.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Cellulose, microcrystalline
Talc
Liquid spray dried glucose
Acacia, spray-dried
Sodium starch glycolate (type A)
Silica colloidal anhydrous
Magnesium stearate
Titanium dioxide
Carnauba wax
Indigo Carmine
Macrogol 6000

6.2 Incompatibilities

Not relevant.

6.3 Shelf-life

The expiry date of the product is indicated on the packaging materials

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and content of container

30 coated tablets in blister (Alu/PVC/PVDC).

6.6 Special requirements for destruction

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Pharma Shalom,
21 Hamelacha st., Ind. Zone Rosh Ha'ayin

8. MANUFACTURER

Soho Flordis International Switzerland SA,VIA MULINI, 6934, Bioggio, Switzerland

9. MARKETING AUTHORIZATION NUMBER

134-16-29935

Revised in June 2021 according to MoH guidelines