

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Valerian Tincture CTS

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution contains 25 mg valerian dry extract
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Drops for oral use.
Almost clear, with some insoluble matter brown liquid, odor and taste of valerian and alcohol.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Valerian Tincture CTS is indicated for relief of mild symptoms of mental stress and to aid sleep for ages 12 and older.

4.2 Posology and method of administration

For oral use.
For adults and children over the age of 12 years: 20-50 drops in a glass of water as required. (see Section 4.4 Special warnings and precautions for use). Do not exceed the recommended dosage.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Do not exceed recommended dose.

4.5 Interaction with other medicinal products and other forms of interaction

Only limited data on pharmacological interactions with other medicinal products are available. Clinically relevant interactions with drugs metabolised by the CYP 2D6, CYP 3A4/5, CYP 1A2 or CYP 2E1 pathway have not been observed.

Additive effects with hypnotics and other sedatives cannot be excluded and therefore co-medication is not recommended as a general precaution.

The effect of Valerian Tincture CTS may be potentiated by alcohol. Excessive concomitant consumption of alcohol should therefore be avoided.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established. As a precautionary measure, because of lack of data, use during pregnancy and lactation is not recommended.

Studies on the effects on fertility have not been performed.

4.7 Effects on ability to drive and use machines

May cause dizziness and impair ability to drive and use machines. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects

Gastrointestinal symptoms, such as nausea, vomiting, abdominal cramps and diarrhoea may occur. Dizziness, headaches and nightmares or vivid dreams may also occur. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or qualified healthcare practitioner should be consulted.

Reporting of 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 at a dose of approximately 20 g caused benign symptoms (fatigue, abdominal cramp, chest tightness, lightheadedness, hand tremor and mydriasis), which disappeared within 24 hours. If symptoms arise, treatment should be supportive.

After intake of very high doses of valerian root over several years (daily consumption corresponding to approximately 10 g) withdrawal symptoms (delirium) have been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: N05CM09

5.2 Pharmacokinetic properties

Not required

5.3 Preclinical safety data

Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Alcohol 95%,
Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

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

6.4 Special precautions for storage

Store at a temperature below 25°C, in the original package in order to protect from light.

6.5 Nature and contents of container

LPDE bottles with LPDE dropper.
Pack sizes: 10 ml and 20ml
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 LICENCE HOLDER AND MANUFACTURER

Ben Shimon Floris Ltd., Industrial Park Misgav, D.N. Misgav 2017400, Israel.

8 REGISTRATION NUMBER:

122-72-30249-00

Revised in 08/2026 according to the MOH guidelines.