

Summary of Product Characteristics**VALERIANE TINCTURA FLORIS****1. NAME OF THE MEDICINAL PRODUCT:**

VALERIANE TINCTURA FLORIS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION :

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

3. PHARMACEUTICAL FORM:

Drops.

Per os.

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

4. CLINICAL PARTICULARS:**4.1 Therapeutic indications:**

VALERIANE TINCTURA FLORIS is indicated for relief of anxiety, stress and nervousness.

4.2 Posology and method of administration: Posology: per os.

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: Known hypersensitivity to the active substance or to any of the additional ingredients contained in the medicine. For the list of the inactive substances - see Section 6.1 " List of excipients ".

4.4 Special warnings and precautions for use:

- Do not drink wine or alcoholic beverages during the treatment with the medicine.
- If you are sensitive to any food or medicine, inform your physician before using this medicine.
- Do not use this medicine frequently, or for a long period, without consulting a physician.

The use of this medicine may impair alertness. Therefore, caution must be exercised when driving a vehicle or operating dangerous machinery and in any activity that requires alertness.

If you are taking, or recently took, other medicines, including over the counter medicines and dietary supplements, inform your doctor or pharmacist.

Pregnancy and Breast-feeding: If you are pregnant, planning to become pregnant or if you are breast-feeding, consult your doctor or pharmacist before using the medicine, since there is insufficient data on the safety of the medication in these conditions.

Important information about some of the ingredients of the medicine: contains alcohol, flammable substance.

Harmful for those suffering from alcoholism. To be taken into account in pregnant, or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.

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 metabolized by the CYP2D6, CYP3A4/5, CYP1A2 or CYP2E1 pathway has not been observed.

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

Contains alcohol and should be avoided in patients taking other medicines known to interact with alcohol.

4.6 Fertility, pregnancy and lactation: The safety of this product during pregnancy and lactation has not been established. Due to the lack of data, use during pregnancy and lactation is not recommended.

4.7 Effects on ability to drive and use machines: May impair ability to drive and use machines. If affected do not drive or operate machinery. This product contains alcohol.

4.8 Undesirable effects: As for any medicine, the use of Valeriane Tinctura Floris may cause side effects in some users, such as nausea or abdominal cramps.

4.9 Overdose: Valerian root at a dose of approximately 20g caused benign symptoms (fatigue, abdominal cramp, chest tightness, light headedness, hand tremor and mydriasis), which disappeared within 24 hours [1]. If symptoms arise, treatment should be supportive. After intake of very high doses of Valerian root over several years (daily consumption corresponding to approximately 30 g of the drug) withdrawal symptoms (delirium) have been reported.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties: Not required as per Article 16c (1) (a) (iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties: Not required as per Article 16c (1) (a) (iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data: The preclinical toxicology data available are limited. Tests on reproductive toxicity and carcinogenicity have not been performed.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients: Alcohol 95%, Purified Water

6.2 Major incompatibilities: not applicable.

6.3 Shelf life: The expiry date of the product is indicated on the bottle. Do not use after the expiry date.

The product may be used after opening until expiry of its validity.

6.4 Special precautions for storage: Store in a cool place, below 25°C.

6.5 Nature and contents of container:

LPDE bottles with LPDE 9mm dropper and PP Capilene QT 80 A 14mm cap.

Pack sizes: 10 ml and 20ml

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal: Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. REGISTRATION NUMBER:

1227230249-00

8. MANUFACTURER:

Ben Shimon Floris Ltd., VAT no. 511126831, Industrial Park Misgav, 2017400, Israel.

9. ISRAELI MARKETING AUTHORIZATION HOLDER:

Ben Shimon Floris Ltd., VAT no. 511126831, Industrial Park Misgav, 2017400, Israel.

10. DATES OF REGISTRATION AND RENEWAL:

First registration: 02/2001

Renewal: 06/2021

11. DATE OF REVISION OF THE TEXT

November 2021

References

[1] Willey LB, Mady SP, Cobaugh DJ, Wax PM. Valerian overdose: a case report. Vet Hum Toxicol. 1995 Aug;37(4):364-5. PMID: 8540231.