

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

VALUSED, 60 mg + 40 mg + 40 mg, soft capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 General description

Oval shape, olive-green colour capsule, with smooth and shiny surface.

2.2 Qualitative and quantitative composition

1 capsule contains:

60 mg of dry extract from *Valeriana officinalis* L. sl., radix (valerian root), (DER 3–4:1), extraction solvent: ethanol 60 % V/V;

40 mg of dry extract from *Humulus lupulus* L., flos (hop strobile), (DER 4-6:1), extraction solvent: methanol 30 % V/V;

40 mg of dry extract from *Passiflora incarnata* L., herba (passion flower), (DER native 4-6:1), extraction solvent: ethanol 90 % V/V;

Excipients which shall be taken into account the medicinal product composition: sorbitol, purified soybean oil.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Soft capsule.

4 CLINICAL PARTICULARS

The efficacy of the product is based exclusively on its long-standing use and experience.

4.1 Therapeutic indications

The product is traditionally used to relieve symptoms of nervous tension as a sedative agent, and in temporary difficulty falling asleep due to nervous conditions.

4.2 Posology and method of administration

Posology

Adults and children over 12 years of age: 2 capsules 2 to 3 times daily.

In difficulty falling asleep: 2 to 3 capsules once daily, half an hour before bedtime.

If the symptoms persist or worsen after 2 weeks of use, a doctor should be consulted.

Children

The safety and efficacy of this product in children aged under 12 years have not been established. This product should not be used in children under 12 years.

Method of administration

The product is administered orally.

4.3 Contraindications

The product should not be used:

- in case of hypersensitivity to the active substances or to any of the excipients listed in section 6.1,
- in case of intolerance to valerian,
- in patients with rarely occurring hereditary fructose intolerance, due to sorbitol content,
- in patients with diagnosed hypersensitivity to peanuts or soybean, due to purified soybean oil content.

4.4 Special warnings and precautions for use

Children and adolescents

The product should not be used in children under 12 years of age due to the lack of clinical data on this patient group.

The product contains sorbitol. It should not be used in patients with rarely occurring hereditary fructose intolerance.

The product contains soya. It should not be used in patients with allergies to peanut or soya.

4.5 Interaction with other medicinal products and other forms of interaction

The product should not be used with other sedatives as the effect of this product may be increased.

4.6 Fertility, pregnancy and lactation

The product is not recommended during pregnancy and lactation due to the lack of data on the safety of valerian, hop and passion flower extracts.

4.7 Effect on ability to drive and use machines

The product may impair psychomotor performance and reduce the ability to drive and use machines.

4.8 Undesirable effects

In general, the product is well tolerated when used at the recommended dosage. Gastrointestinal disorders were observed in patients with poor tolerance to valerian root.

Isolated cases of nausea and accelerated heart rate (tachycardia) were observed after administration of passion flower.

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. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting systems.

4.9 Overdose

The product is completely safe when used at the recommended dosage.

Long-term use of high doses (approx. 20 g of the raw material daily, which corresponds to approx. 97 capsules), especially in individuals sensitive to valerian, may cause overdose symptoms such as fatigue, lower abdominal cramps, difficulty breathing, heart rhythm disorders, vertigo, hand tremors and pupillary dilation.

If any of the above-mentioned symptoms are observed, the patient should stop taking the product.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: other hypnotics and sedatives, ATC code: N05CM

The product contains extracts of three herbal raw materials: valerian root, hop strobiles and passion flower. It is traditionally used in temporary nervous tension as a sedative and sleep-inducing agent.

The medicinal product relieves symptoms of nervous tension such as:

- accelerated heartbeat due to nervousness,
- restlessness and hand tremor,
- gastric disorders due to nervous conditions,
- difficulty concentrating due to nervous conditions.

5.2 Pharmacokinetic properties

There are no pharmacokinetic data regarding dry extracts of valerian root, hops strobile and passion flower.

5.3 Preclinical safety data

No preclinical studies have been conducted with VALUSED, soft capsules.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified soybean oil
Soybean lecithin
Hydrogenated coconut oil
Refined palm oil
Yellow wax

Gelatin capsule components:

Gelatin
Glycerol
Sorbitol (dry residue of 70% sorbitol solution)
Titanium dioxide (E 171)
Black iron oxide (E 172)
Yellow iron oxide (E 172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store in closed, original package, below 25°C.

6.5 Nature and contents of container

2 PVC/PCTFE/PVC/Aluminium blisters containing 15 capsules each, in a carton box along with the insert-leaflet.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder and Manufacturer

P.P.F. "Hasco-Lek" S.A.

242 E Zmigrodzka str., 51-131 Wroclaw, Poland

+48 71 352 95 22

8 8. MARKETING AUTHORISATION NUMBER

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

July 2022