

SUMMARY OF PRODUCT CHARACTERISTICS

NITEHERB

1 NAME OF THE MEDICINAL PRODUCT

Niteherb® Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each coated tablet contains:

150 mg of extract (as dry extract) from Valerian root (*Valerian officinalis L.*)(equivalent to 450-900 mg of Valerian root).

Extraction solvent: Ethanol 70% v/v.

One coated tablet contains 35 mg of glucose and 136 mg of sucrose.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Coated tablet.

White, glossy, round, biconvex.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for the temporary relief of sleep disturbances due to symptoms of mild anxiety based on traditional use only.

4.2 Posology and method of administration

For oral short term use only.

For adults and the elderly take 1 to 2 tablets half an hour before bedtime. If necessary, an additional tablet can be taken earlier in the evening. The tablets should not be chewed.

As treatment effects may not be apparent immediately, NiteHerb should be taken for 2-4 weeks continuously.

If symptoms worsen or do not improve after 4 weeks a doctor or qualified healthcare practitioner should be consulted.

Not for children or adolescents under 18 years.

4.3 Contraindications

Hypersensitivity to Valerian or any of the constituents in this product

The product should not be used in children or adolescents under 18 years of age.

4.4 Special warnings and precautions for use

This product contains glucose.

1 coated tablet contains max. 35mg of glucose.

This product contains sucrose.

1 coated tablet contains max. 136mg of sucrose or 0,21 carbohydrate units.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine

4.5 Interaction with other medicinal products and other forms of interaction

Only limited data on pharmacological interactions with other medicinal products are available. Additive effects with hypnotics and other sedative drugs cannot be excluded and therefore co-medication is not recommended as a general precaution.

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

4.6 Pregnancy and lactation

Safety 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 the ability to drive and use machines. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects

Gastrointestinal symptoms, such as nausea, abdominal cramps, may occur. The frequency is not known.

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

4.9 Overdose

Valerian root at a dose of approximately 20 g (equivalent to 10 tablets) 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 30 g of the drug) withdrawal symptoms (delirium) have been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 *List of excipients*

Liquid glucose, spray dried
Silica, colloidal anhydrous
Cellulose, powdered
Croscarmellose sodium
Stearic acid
Talc
Sucrose
Calcium carbonate E170
Acacia
Tragacanth
Titanium dioxide E 171
Capol 600 T.S. containing:
 Beeswax, white
 Carnauba wax
 Shellac

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life is 3 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Original packages contain 30 or 60 coated tablets

NiteHerb tablets are packed in PVC/ PVDC- aluminium blisters and inserted into a carton.

6.6 Special precautions for disposal

No special requirements

7 REGISTRATION HOLDER

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8 REGISTRATION NUMBER

THR 23056/0006

9 DATE OF FIRST REGISTRATION AUTHORISATION

19th December 2007

10 DATE OF REVISION OF THE TEXT