SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Kalms Night One-A-Night
Nytol Herbal Simply Sleep One-A-Night Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 385 mg of extract (as dry extract) from *Valeriana officinalis* L., radix (equivalent to 1.54 – 1.93 g of Valerian root).
Extraction solvent: Ethanol 60% V/V.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film coated tablet

White, ovaloid

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for the temporary relief of sleep disturbances, based on traditional use only.

4.2 Posology and method of administration

For oral use.

Adults and the elderly: One tablet to be taken 30-60 minutes before bedtime.
One additional tablet can be taken earlier during the evening if necessary.

As treatment effects may not be apparent immediately, Kalms Night One-a-Night should be taken for 2-4 weeks continuously.

Duration of use:
If symptoms worsen, or do not improve after 4 weeks, a doctor or qualified healthcare practitioner should be consulted.

The use in children or adolescents under 18 years of age is not recommended (see Section 4.4. Special warnings and precautions of use).

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients

4.4 Special warnings and precautions for use

Do not exceed stated dose.

The use of this product in children or adolescents under 18 years of age is not recommended because data are not sufficient and medical advice should be sought.

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

This medicine contains less than 1 mmol sodium (23mg) per 1 tablet dose, that is to say essentially “sodium-free”.

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 this product 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. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

Valerian root at a dose of approximately 20 g (equivalent to 8 to 13 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

Reverse mutation assays (Ames test) on bacteria indicated that the product was not mutagenic in *Salmonella typhimurium* (strains TA 98, TA 100, TA 102, TA 1535 and TA 1537) mutation assays with or without metabolic activation..

Tests on reproductive toxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Extract excipients

Maltodextrin
Colloidal anhydrous silica

Tablet Core
Croscarmellose Sodium
Magnesium Stearate
Prosolv SMCC50 (Silicified Microcrystalline Cellulose)
Talc
Silicon Dioxide

Tablet Coating
Opadry (TM) 07F28588 White (Hypromellose, Talc, Titanium Dioxide, PEG, Saccharin Sodium)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

Store in the original package.

6.5 Nature and contents of container

14, 21, 28, 42 or 56 tablets stored in PVC/Aclar®-aluminium/polyethylene laminate blister packs.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

THR 01074/0002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/07/2018

10 DATE OF REVISION OF THE TEXT

10/03/2025