Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Noctura 6C tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Coffea arabica 6C
Passiflora incarnata 6C
Potassium bromide 6C
Valeriana officinalis 6C

Excipient(s) with known effect:
Lactose 174.26 mg
Sucrose 42.39 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
Biconvex circular white to off-white tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A Homeopathic Medicinal product used within the homeopathic tradition to aid sleep and for the temporary relief of sleep disturbances.

4.2 Posology and method of administration

For oral use
Adults and the elderly: Take 2 tablets 4 hours before retiring and 2 tablets immediately before retiring. A further 2 tablets may be taken during the night if required.
Tablets to be sucked or chewed.
Not recommended for use in adolescents or children under 18 years of age.
If the symptoms worsen, or persist after 7 days, a doctor or qualified healthcare practitioner should be consulted.

4.3 Contraindications

Hypersensitivity to any of the active ingredients or any of the excipients.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.
This product is not recommended for use in adolescents or children under 18 years of age and medical advice should be sought.
If symptoms worsen, or persist after 7 days, a doctor or qualified healthcare practitioner should be consulted.
Contains lactose and sucrose - Patients with rare hereditary problems of fructose intolerance, galactose intolerance, the Lapp lactase deficiency, glucose-galactose malabsorption or sucrose-insomaltese insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interactions

None known

4.6 Fertility, pregnancy and lactation

Pregnancy and lactation: There is no evidence of the safety of the product in human pregnancy or lactation, nor is there any evidence from animal studies. Although no adverse events have been observed, the use of this product during pregnancy and lactation should be avoided unless under the guidance of a doctor.
Studies on the effects on fertility have not been performed.

4.7 Effects on ability to drive and use machines

Studies on the effects on the ability to drive or use machinery have not been performed.

4.8 Undesirable effects

None known
If any adverse reactions occur, a doctor or pharmacist 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 of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

No reports

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Sucrose
Stearic acid
Magnesium stearate

6.2 Incompatibilities

Not known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C. Store in the original packaging in order to protect from moisture.

6.5 Nature and contents of container

Aluminium/PVC blister strips packed in a cardboard carton
Pack size: 72 tablets

6.6 Special precautions for disposal

No special precautions for disposal.

7 MARKETING AUTHORISATION HOLDER

A. Nelson & Company Limited
5-9 Endeavour Way
Wimbledon
London
SW19 8UH
United Kingdom

8 MARKETING AUTHORISATION NUMBER

HOA1149/003/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of First Registration: 15th May 2020

10 DATE OF REVISION OF THE TEXT