Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Quiet Life Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

	mg/tablet
Leonurus cardiaca powder (Motherwort)	34
Humulus lupulus powder (Hops)	75
Passiflora incarnata powder (Passiflora)	58
Valeriana Dry Hydroalcohotic extract (equivalent to 50 mg *Valeriana officinalis* L. root)	12.5
Thiamine hydrochloride	0.71
Riboflavin	0.57
Nicotinamide	4.49

Excipients:

Sucrose	167.77

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Coated Tablet (tablet).
Pink sugar coated round, biconvex coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

To relieve irritability and exogenous stresses and strains and induce relaxation.

4.2 Posology and method of administration

Two tablets two to three times daily. Use should not exceed two weeks.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients.
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.4 Special warnings and precautions for use

The recommended dosage should not be exceeded.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Should not be taken by women who are pregnant or likely to become pregnant except on the advice of a doctor or antenatal clinic.

4.7 Effects on ability to drive and use machines

Quiet Life Tablets have minor or moderate effect on the ability to drive and use machines. May impair ability to drive and use machines. Affected patients should not drive or operate machinery.

4.8 Undesirable effects

None Known.

4.9 Overdose

There have been no recorded problems and no special procedures or antidotes are known.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Hypnotics and sedatives in combination, excluding barbiturates, N05CX.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Calcium carbonate
Talc
Sodium starch glycolate (Type A)
Acacia
Stearic acid
Shellac Varnish
Lactuca virosa powdered extract (wild lettuce)
Magnesium stearate
Colloidal hydrated silica
Yellow Beeswax
Carnauba wax
Mastercote SPO415G Pink*
* containing (red iron oxide E172, Titanium Dioxide E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 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

Tablet container (type III glass) with a screw cap (HDPE/LLDPE). Contents 50 or 100 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirement.

7 MARKETING AUTHORISATION HOLDER

G.R. Lane Health Products Ltd.
Sisson Road
Gloucester
GL2 0GR
UK

8 MARKETING AUTHORISATION NUMBER

PA 257/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 November 1992

Date of last renewal: 27 November 2007

10 DATE OF REVISION OF THE TEXT

October 2008