

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

RelaxHerb coated tablets
Lloydspharmacy Stress Relief coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 coated tablet contains 425mg of extract (as dry extract aqueous ethanolic 50% v/v) from Passion flower (*Passiflora incarnata* L.)(equivalent to 2125 – 2975 mg of Passion flower).

Each coated tablet contains 187 mg of sucrose and 5 mg of glucose.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Coated tablet.
Light-yellow, round, biconvex, smooth glossy surface without ruptures.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for the temporary relief of symptoms associated with stress such as mild anxiety based on traditional use only

4.2 Posology and method of administration

For oral short term use only. The patient should consult a healthcare practitioner if symptoms worsen or do not improve after 4 weeks.

For adults and the elderly, take 1 tablet daily if required. Tablets should be swallowed whole with a little liquid. The tablets should not be chewed.

This product is not indicated for use in patients less than 18 years old.

4.3 Contraindications

Hypersensitivity to Passion flower or any of the other ingredients in this product.
Pregnancy
Lactation
Patients under 18 years of age.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

If the condition worsens, or if symptoms persist for more than four weeks, or if adverse effects not mentioned in the package leaflet occur, consult a healthcare practitioner.

This product contains glucose.
1 coated tablet contains max. 5mg of glucose.

This product contains sucrose.
1 coated tablet contains max. 187mg of sucrose or 0,29 carbohydrate units.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Although no clinical data about interactions with synthetic sedatives are available, concomitant use with synthetic sedatives (such as benzodiazepines) is not recommended.

4.6 Pregnancy and lactation

The safety of the product during pregnancy and lactation has not been established. Use during pregnancy and lactation is not recommended.

4.7 Effects on ability to drive and use machines

May cause drowsiness and impair the ability to drive and operate machines. If affected, do not drive or operate machines.

4.8 Undesirable effects

One case of hypersensitivity (vasculitis) and one case of nausea and tachycardia have been reported. The frequency is not known.
If other adverse reactions not mentioned above occur, a doctor or a qualified healthcare practitioner should be consulted.

4.9 Overdose

No case of overdose has been reported. Symptomatic and supportive measures should be taken as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended., unless necessary for the safe use of the product.

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Extract excipients:

Maltodextrin
Silica, colloidal anhydrous

Tablet core:

Maltodextrin
Silica, colloidal anhydrous
Cellulose, powdered
Croscarmellose sodium
Magnesium stearate
Stearic acid
Talc

Coating:

Sucrose
Talc
Calcium carbonate E170
Acacia
Tragacanth
Titanium dioxide E171
Liquid glucose, spray dried

Iron oxide hydrate E172 (=yellow iron oxide)
Hypromellose
Capol 600 T.S. containing:
Beeswax, white
Carnauba wax
Shellac

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life is 4 years

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Original packages contain 21, 30, 60 and 90 coated tablets

RelaxHerb coated 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 23056/0008

9 DATE OF FIRST REGISTRATION

Summary of Product Characteristics
RelaxHerb Approved

2nd July 2009

26th February 2009