

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

DiaPassion Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each coated tablet contains:

425 mg of extract (as dry extract) from Passion flower herb (*Passiflora incarnata* L.) (5-7:1) (equivalent to 2125-2975 mg of Passion flower herb).

Extraction solvent: Ethanol 50% v/v

Excipients: 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. Tablets should be swallowed whole with a little liquid. The tablet 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 ingredient 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. 5 mg glucose.

This product contains sucrose.

1 coated tablet contains max. 187 mg 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 or 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, patients should 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 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

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

Coating

Sucrose
Talc
Calcium carbonate E170
Acacia
Tragacanth
Titanium dioxide E 171
Liquid glucose, spray dried
Iron oxide hydrate E 172 (= 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 30, 60, 90 or 100 coated tablets

DiaPassion Tablets are packed in PVC/ PVDC- aluminium blisters and inserted into a carton.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Diapharm Regulatory Services GmbH
Würzburger Str. 3
26121 Oldenburg
Germany

8 MARKETING AUTHORISATION NUMBER(S)

THR 33518/0008

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/07/2009

10 DATE OF REVISION OF THE TEXT

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