

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

DiaSleep Plus tablets

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each coated tablet contains:

125 mg of extract (as dry extract) from Valerian root (*Valeriana officinalis* L.) (3-6:1) (equivalent to 375 – 750 mg of Valerian root).

Extraction solvent: Ethanol 70% v/v,

and

250 mg of extract (as dry extract) from Passion flower herb (*Passiflora incarnata* L.) (5-7:1) (equivalent to 1250 – 1750 mg of Passion flower herb).

Extraction solvent: Ethanol 50% v/v

Excipients: each coated tablet contains 187 mg of sucrose and 32 mg of glucose.

For full list of excipients, see section 6.1

### **3 PHARMACEUTICAL FORM**

Coated tablet.

Light-yellow, round, biconvex, smooth glossy surface.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

A traditional herbal medicinal product used for the temporary relief of sleep disturbances due to symptoms of mild anxiety, based on traditional use only.

#### **4.2 Posology and method of administration**

For oral short term use only.

For adults and the elderly, take one to two tablets half an hour before bedtime. Tablets should be swallowed whole with some water or other liquid. The tablets should not be chewed.

As treatment effects may not be apparent immediately, DiaSleep Plus should be taken for at least 2 weeks continuously.

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

Not for children or adolescents under 18 years.

#### **4.3 Contraindications**

Hypersensitivity to Valerian, Passion Flower or any of the excipients in the product.

The product should not be used in children or adolescents under 18 years.

#### **4.4 Special warnings and precautions for use**

Do not exceed the stated dose.

This product contains sucrose and glucose.

1 sugar-coated tablet contains max. 187 mg of sucrose and a max. 32 mg glucose.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Only limited data on pharmacological interactions with other medicinal products are available. Additive effects with hypnotics and other sedative drugs cannot be excluded and therefore co-medication is not recommended as a general precaution.

The effect of DiaSleep Plus may be potentiated by alcohol. Excessive concomitant consumption of alcohol should therefore be avoided.

#### **4.6 Pregnancy and lactation**

The safety of the product during pregnancy and lactation has not been established. Therefore it should be avoided during pregnancy or lactation.

#### **4.7 Effects on ability to drive and use machines**

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

#### **4.8 Undesirable effects**

Gastrointestinal symptoms, such as nausea, abdominal cramps, may occur. The frequency is not known. One case of hypersensitivity (vasculitis) and one case of tachycardia have been reported with Passion Flower. 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**

Valerian root at a dose of approximately 20 g (equivalent to 10 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.

After intake of very high doses of Valerian root over several years (daily consumption corresponding to approximately 30 g of the drug) withdrawal symptoms (delirium) have been reported.

No cases of overdose have been reported for Passion Flower.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Not applicable.

### **5.2 Pharmacokinetic properties**

Not applicable.

### **5.3 Preclinical safety data**

The preclinical toxicology data available are limited. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

#### Tablet core

Maltodextrin

Silica, colloidal anhydrous

Cellulose, powdered

Croscarmellose sodium

Magnesium stearate

Stearic acid

Talc

Liquid glucose, spray dried

#### 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
- DiaSleep plus coated 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 33518/0001
- 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**  
22/12/2008
- 10 DATE OF REVISION OF THE TEXT**  
22/12/2008
- 1 NAME OF THE MEDICINAL PRODUCT**  
DiaNight Plus tablets
- 2 QUALITATIVE AND QUANTITATIVE COMPOSITION**  
Each coated tablet contains:
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- Extraction solvent: Ethanol 70% v/v,
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#### **4.2 Posology and method of administration**

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For adults and the elderly, take one to two tablets half an hour before bedtime. Tablets should be swallowed whole with some water or other liquid. The tablets should not be chewed.

As treatment effects may not be apparent immediately, DiaNight Plus should be taken for at least 2 weeks continuously.

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

Not for children or adolescents under 18 years.

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