

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE MEDICINAL PRODUCT

Vitano Film-coated Tablets  
Boots Stress Relief film-coated tablets

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains:

200 mg of extract (as dry extract) from *Rhodiola rosea* L. roots and rhizomes (1.5 – 5: 1) (WS® 1375) (equivalent to 300 – 1000 mg of *Rhodiola rosea* roots and rhizomes)

Extraction agent: ethanol 60 % (m/m)

For a full list of excipients see section 6.1.

## 3. PHARMACEUTICAL FORM

Film-coated tablet; round, red tablet.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

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

### 4.2 Posology and method of administration

*Adults and the elderly*

Two tablets daily, one before breakfast and one before lunch, to be taken with a glass of water, preferably 30 minutes before food intake.

*Children and adolescents less than 18 years old*

Use in children and adolescents under 18 years of age is not recommended (see Section 4.4).

*Hepatic and renal impairment*

Use in patients with impaired hepatic or renal function is not recommended (see Section 4.3).

#### **Duration of use**

If the symptoms worsen or persist for more than 2 weeks a doctor or a qualified healthcare practitioner should be consulted.

Not to be taken for more than 2 months.

### 4.3 Contraindications

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

Children and adolescents under the age of 18 years.

Patients with impaired hepatic or renal function.

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

This product is intended for relief of symptoms associated with stress. Patients with signs and symptoms of depression should seek medical advice for appropriate treatment.

The use in children and adolescents under 18 years of age and in patients with impaired hepatic and renal function is not recommended because data are not sufficient and medical advice should be sought.

Keep out of the sight and reach of children.

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

*In vitro*, *Rhodiola rosea* extract at a concentration of 10 microgram/ml resulted in inhibition of CYP2C9 and CYP2C19 isoenzymes. The clinical relevance of these findings is not known.

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

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

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

No studies on the effects on the ability to drive and use machines have been undertaken.

#### **4.8 Undesirable effects**

There have been sporadic case reports of hypersensitivity and hypoglycaemia. There is no clear relationship between the development of hypoglycaemia and the use of *Rhodiola rosea* extract.

#### **4.9 Overdose**

No case of overdose has been reported.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: tonics, ATC code: A13A

Not applicable.

#### **5.2 Pharmacokinetic properties**

Not applicable.

#### **5.3 Preclinical safety data**

Non-clinical data on *Rhodiola rosea* extract revealed no special hazard for humans based on limited studies of single-dose toxicity, repeated-dose toxicity and mutagenicity.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Microcrystalline cellulose, croscarmellose sodium, precipitated silicon dioxide, magnesium stearate, hypromellose, stearic acid, iron oxide red (iron (III) oxide), titanium dioxide, anti foam emulsion.

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf life**

3 years.

Vitano should not be used after the expiry date which is stated on the outer carton and blister.

## **6.4 Special precautions for storage**

This medicinal product does not require any special storage conditions.

## **6.5 Nature and contents of container**

The film-coated tablets are sealed into blisters made of PVC/PVDC and aluminium foil packed into a cardboard box together with the package leaflet. Vitango is available in packs with 25, 30, 50, 60, 90, 100 and 120 tablets. Not all pack sizes may be marketed.

## **6.6 Special precautions for disposal and other handling**

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

## **7. MARKETING AUTHORISATION HOLDER**

Dr. Willmar Schwabe GmbH & Co. KG  
Willmar-Schwabe-Str. 4  
D-76227 Karlsruhe  
GERMANY

### **UK distributor:**

Schwabe Pharma (UK) Ltd  
Alexander House, Mere Park,  
Dedmere Road,  
Marlow, Bucks, SL7 1PD

## **8. MARKETING AUTHORISATION NUMBER(S)**

THR 05332/0004

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

24/07/2008

## **10. DATE OF REVISION OF THE TEXT**

29/6/2009