

## **Vitano Film-coated Tablets**

**THR 05332/0004**

**UKPAR**

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## VITANO FILM-COATED TABLETS

**THR 05332/0004**

### **LAY SUMMARY**

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Dr. Willmar Schwabe GmbH & Co. KG a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Vitano Film-coated Tablets (Traditional Herbal Registration number: 05332/0004). This product is available without prescription and can be bought from pharmacies and other outlets.

Vitano Film-coated Tablets are used for the temporary relief of symptoms associated with stress, such as fatigue, exhaustion and mild anxiety, based on traditional use only. The tablets' active ingredient is dry extract from *Rhodiola rosea* L. rhizome and root.

This registration is based exclusively upon evidence of traditional use of *Rhodiola rosea* as a herbal medicine and not upon data generated from clinical trials. There is no requirement under the Traditional Herbal Registration scheme to prove scientifically that the product works.

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a Traditional Herbal Registration Certificate could be granted.

# **VITANO FILM-COATED TABLETS**

**THR 05332/0004**

## **SCIENTIFIC DISCUSSION**

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## **INTRODUCTION**

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Vitano Film-coated Tablets to Dr. Willmar Schwabe GmbH & Co. KG on 24 July 2008. This product is on the general sales list (GSL).

The application was submitted under Article 16.c of Directive 2001/83 EC, as amended, as part of the Traditional Herbal Medicines Registration Scheme.

This product consists of tablets containing 200 mg of dry extract from the roots and rhizomes of *Rhodiola rosea* L. The product is used for temporary relief of symptoms associated with stress such as fatigue, exhaustion and mild anxiety. This THR is based exclusively on evidence of traditional use of *Rhodiola rosea*. The recommended dose is two tablets daily.

The data supplied by the applicant demonstrate 30 years of traditional use of *Rhodiola rosea* in the European Community. A satisfactory review of the available safety data on *Rhodiola rosea* has also been provided, together with an expert safety report supporting the proposed product.

## **PHARMACEUTICAL ASSESSMENT**

**HERBAL SUBSTANCE:** *RHODIOLA ROSEA* L.

### **General information**

**Latin name:** *Rhodiola rosea* L.

**Common name:** Artic rose, Golden root, Roseroot

**Family:** Crassulaceae

**Parts of plant used:** root and rhizome

**Cultivation/collection area:** Russia (Altai region), Kazakhstan, Mongolia, Ukraine, Romania (Carpathian region) Bulgaria (Balkan region), Canada, Finland, Germany

### **Manufacture**

*Rhodiola rosea* is a perennial succulent. The plants used to make Vitano Film-coated Tablets are either grown in the wild or cultivated in Russia (Altai region), Kazakhstan, Mongolia, Ukraine, Romania (Carpathian region) Bulgaria (Balkan region), Canada, Finland or Germany. The documentation confirms that the herbal substance is produced in accordance with the principles of Good Agricultural and Collection Practice (GACP). Satisfactory assurance has been provided that there are no pre- and post-harvest chemical treatments used to produce the herbal substance.

The companies responsible for collecting the plant from the wild use trained botanists and assess the areas prior to the start of collection and exclude areas where other species that could be potential contaminants occur.

### **Control of Herbal Substance**

An appropriate specification based on the Ph Eur monograph for *Rhodiola rosea* root is used. This is acceptable.

Analytical methods are satisfactory for ensuring compliance with the relevant specifications. The specification is supported by the batch data provided.

### **Container closure system**

A suitable container is used to store the herbal substance, which is kept under dry conditions at room temperature.

### **Stability**

Stability data for the herbal substance are not available. However, confirmation is provided that the dried herbal substance will be tested immediately prior to making the herbal preparation, therefore, stability data are not required.

## **HERBAL PREPARATION: *RHODIOLA ROSEA* ETHANOLIC EXTRACT**

### **General information**

#### Nomenclature

Name: *Rhodiola rosea* root and rhizome ethanolic extract  
Part of plant: Root and rhizome  
Drug to Extract Ratio (DER native): 1.5 – 5: 1  
Extractant (Extraction solvent): Ethanol 60% m/m.

### **Manufacture**

A satisfactory description and flow-chart of the manufacturing method has been provided.

An up to date GMP certificate has been provided for the manufacturing site.

#### Control of Materials

The solvents (purified water and ethanol) used for extraction comply with their respective Ph Eur monographs. Suitable certificates of analysis have been provided.

#### Controls of Critical Steps and Intermediates

Satisfactory in-process controls are performed during manufacture of the herbal preparation.

#### Process Validation and/or Evaluation

Process validation has been carried out using batches of extract. The validation studies support the manufacturing process.

### **Characterisation**

Suitable tests are performed to elucidate the structure and other characteristics of the herbal preparation. Microbial quality of the herbal preparation is controlled in line with the Ph. Eur.

### **Control of Herbal Preparation**

#### Specification

A satisfactory specification, with appropriate tests and limits has been provided for the herbal preparation

#### Analytical Procedures/ Validation of Analytical Procedures

Analytical methods are either those of the Ph Eur or have been fully validated.

#### Batch Analyses

Batch analysis data are provided and these comply with the proposed specification.

#### Justification of Specification

The proposed specification has been justified satisfactorily.

### **Reference Standards or Materials**

Suitable details have been provided for the reference standards. Satisfactory certificates of analysis have been provided.

### **Container Closure System**

The herbal preparation is stored in a suitable container closure system. A description of the container closure system and its specifications are provided. The stability data provided show no incompatibilities between the herbal preparation and the container. Confirmation is provided that the components of the containers comply with Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs.

## **Stability**

Batches were packed in the container closure system and stored under ICH real time, intermediate and accelerated conditions. The samples were tested according to the herbal preparation specification tests. The results support the storage conditions and shelf life.

## **HERBAL PRODUCT**

### **Description and Composition of the Herbal Product**

Vitano Film-coated Tablets are immediate-release, film-coated tablets containing 200 mg of the herbal preparation *Rhodiola rosea* ethanolic extract.

As well as the herbal preparation, the finished product contains microcrystalline cellulose, croscarmellose sodium, precipitated silicon dioxide, magnesium stearate, hypromellose, stearic acid, iron oxide red (iron (III) oxide), titanium dioxide and anti foam emulsion. The excipients used are conventional pharmacopoeial substances used in the manufacture of solid dosage forms containing herbal preparations.

### **Manufacture**

A flow diagram summarising the manufacturing process and in-process controls has been provided. The manufacturing process consists of standard manufacturing methods: mixing, tableting and film-coating.

### Control of Critical Steps and Intermediates

A number of in-process control tests are performed during the manufacturing process. All are considered adequate.

### Process Validation and/or Evaluation

The applicant has committed to perform full process validation on three production scale batches of the finished product when these are available and to report any anomalous results to the licensing authorities.

### **Control of Excipients**

All of the excipients comply with their respective current European Pharmacopoeial monograph, with the exception of precipitated silica and iron oxide red (in the absence of a Ph Eur monograph, this is acceptable). The precipitated silica complies with the DAB and a certificate of analysis has been provided. Iron oxide red complies with an in-house specification and a suitable certificate of analysis has been provided.

Both the magnesium stearate and stearic acid used in these tablets are exclusively of plant origin and, thus, do not hold any risk for TSE.

### **Control of Herbal Product**

#### Specification

The finished product specifications at release and end of shelf life are detailed and the tests and limits applied were found to be satisfactory for a product of this nature.

#### Analytical Procedures

Satisfactory details have been provided on all analytical procedures and these analytical procedures are valid.

#### Batch Analyses

Satisfactory batch data have been provided to support the specifications.

#### Justification of Specification(s)

The proposed release and shelf-life specifications have, in general been adequately justified with respect to the parameters controlled and the limits applied.

#### **Reference Standards or Materials**

Suitable details have been provided for the reference standard. A satisfactory certificate of analysis has been provided.

#### **Container Closure System**

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

Confirmation is provided that all components of the blister pack comply with Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs.

#### **Stability**

Stability studies have been conducted under ICH conditions (long term, accelerated). The tablets were tested in accordance with the finished product specification using the same test methods. The results support the proposed shelf life of 3 years with the storage precaution "Vitano should not be used after the expiry date which is stated on the outer carton and blister."

#### **ASSESSOR'S COMMENTS ON THE SUMMARY OF PRODUCT CHARACTERISTICS, LABEL AND PATIENT INFORMATION LEAFLET**

All product literature is satisfactory.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

#### **ASSESSOR'S OVERALL CONCLUSIONS ON QUALITY**

A Traditional Herbal Registration can be granted.



## **NON-CLINICAL ASSESSMENT**

### **NONCLINICAL ASPECTS**

The Expert Safety Report submitted by the applicant lists relevant references to published work studying the toxicology of *Rhodiola rosea*.

### **NONCLINICAL OVERVIEW**

The applicant has submitted a good literature review with this application. An Expert Report on Safety was provided, which included reviews of some non-clinical data. The Expert Safety Report was written by a suitably qualified expert.

The overview submitted in support of this application is satisfactory.

Due to a shortage of published data on *Rhodiola rosea*, it is not possible to assess if the safety package for the phytochemical constituents of *Rhodiola rosea* is acceptable to the standards of today's GLP and safety testing requirements. However, the information supplied demonstrating traditional use is acceptable and, thus, the lack of provision of a complete standard safety package is acceptable and in compliance with guideline EMEA/HMPC/32116/05.

Data in the literature regarding the genotoxic potential of the product is deficient. Therefore, *Rhodiola rosea* was tested for mutagenic potential. WS® 1375 did not reveal any mutagenic effect up to a cytotoxic concentration of 3,160 µg/ plate in an Ames test, with and without metabolic activation. According to the draft guidance on the assessment of genotoxic constituents in herbal substance/preparations, no further genotoxicity studies are required at this stage.

### **SUMMARY OF PRODUCT CHARACTERISTICS (SPC)**

The SPC for this product is satisfactory from a preclinical point of view.

### **ENVIRONMENTAL RISK ASSESSMENT**

An environmental risk assessment is not required for herbal medicinal products according to guidance CPMP/SWP/4447/00.

### **CONCLUSION**

The information supplied demonstrating traditional use of *Rhodiola rosea* is acceptable. An adequate literature review of *Rhodiola rosea* has been carried out by the applicant and the genotoxicity testing was satisfactory. Granting of a THR is acceptable.

## **CLINICAL ASSESSMENT**

### **LEGAL STATUS**

The Herbal Medicines Advisory Committee (HMAC) considered *Rhodiola rosea* acceptable for the General Sales List for internal use.

### **PROPOSED INDICATION**

The applicant has proposed the following:

‘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.’

### **Assessor’s comment**

This is acceptable

### **EVIDENCE OF LONG-STANDING USE**

Article 16 c 1 (c) requires the Applicant to provide bibliographic or expert evidence to show that the medicinal product in question, or a corresponding product, has been in medicinal use throughout a period of at least 30 years, including at least 15 years within the Community.

*Rhodiola rosea* is well known in herbal medicine as an adaptogen and has been used for centuries in the traditional medicines of Russia and Scandinavia. The Applicant has provided evidence for the use of *Rhodiola rosea* as 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 within the EU for a period exceeding 30 years.

### **Assessor’s comment:**

The information provided to demonstrate that *Rhodiola rosea* root and rhizome has been in use for at least 30 years, of which at least 15 years have been in an EU Member State, is satisfactory.

### **SAFETY REVIEW**

Article 16 c 1 (D) requires the Applicant to provide a bibliographic review of safety data, together with an expert report. These have been provided and are satisfactory.

### **Assessor’s comment:**

The applicant has undertaken an adequate safety summary. The summary reveals few adverse events associated with the use of this product.

### **PRODUCT LITERATURE**

All product literature is satisfactory.

The package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

### **ASSESSMENT OF SUITABILITY FOR GSL STATUS FOR RHODIOLA ROSEA**

Section 51 of the Medicines Act 1968 states that “GSL may be appropriate for medicines which can, with reasonable safety, be sold or supplied otherwise than by or under the supervision of a pharmacist”. The term “reasonable safety” may usefully be defined as: “Where the hazard to health

and the risk of misuse and the need for special precautions in handling are small, and where wider sale would be a convenience to the purchaser”.

Suitability of indication for GSL:

1. Hazard to health: There appears to be a low risk of hazard to health in the proposed indication.
2. Risk of misuse: There appears to be minimal risk of misuse of this product.
3. Need to take special precautions in handling: No special precautions required.
4. Wider sales are convenient to the purchaser: This would apply.

In summary, it is considered that the four above mentioned criteria have been met and this product is suitable for GSL status.

## **DISCUSSION**

The data supplied by the Applicant are sufficient to demonstrate the 30 years of traditional use within the European Community required for registration under the Traditional Herbal Medicines Product Directive. A review of the available safety data relating to *Rhodiola rosea* has been provided, together with an expert report supporting the registration of the product. A number of amendments are required to the SPC to ensure safe use of the product. The changes to the SPC will require changes to the patient information leaflet and labelling.

## **RECOMMENDATIONS**

A Traditional Registration may be granted.

## **OVERALL CONCLUSION AND RISK ASSESSMENT**

### **QUALITY**

The quality data submitted with this application are satisfactory.

### **PRECLINICAL**

No new preclinical data were submitted and none are required for an application of this type.

### **EFFICACY AND SAFETY**

No clinical efficacy data are required for registration of Traditional Herbal Medicinal Products (THMP).

The Applicant has provided a bibliographic review which shows ample evidence for the use of *Rhodiola rosea* within the EU for a period exceeding 30 years.

A satisfactory review of the safety data has been provided.

The SPC, PIL and labelling are satisfactory.

### **RISK ASSESSMENT**

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified.

## **VITANO FILM-COATED TABLETS**

**THR 05332/0004**

### **STEPS TAKEN FOR ASSESSMENT**

- 1 The MHRA received the Traditional Herbal Registration application on 23 November 2007
- 2 Following standard checks and communication with the applicant the MHRA considered the application valid on 28 January 2008
- 3 The application was referred to the Herbal Medicine Advisory Committee for advice on 9 April 2008. Following this, the MHRA requested further information relating to the dossier on 28 April 2008
- 4 The applicant responded to the MHRA's requests, providing further information on the dossier on 22 July 2008
- 5 A THR was granted on 24 July 2008

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Vitano 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 Interaction 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. Vitano 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**

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**

24/07/2008



**PATIENT INFORMATION LEAFLET**

# Vitano<sup>®</sup> film-coated tablets

*Rhodiola rosea* root extract 200mg



**Please read this leaflet carefully before you start taking these tablets.**  
It contains some important information about Vitano.

**Keep this leaflet with the tablets.**

You may want to read it again or show it to your doctor, pharmacist or healthcare practitioner.

## What is in this leaflet

1: What this product is and what it is used for .....	page 1
2: Before you take this product.....	page 2
3: How to take this product .....	page 2
4: Side-effects .....	page 3
5: After taking this product .....	page 3
6: Product description .....	page 4

## 1: What this product is and what it is used for

Each film-coated tablet of this product contains 200mg of extract (as dry extract) from *Rhodiola rosea* L. rhizome and root (1.5-5:1) (WS<sup>®</sup> 1375) (equivalent to 300-1000mg of *Rhodiola*). Extraction solvent: Ethanol 60% m|m.

**Vitano is a traditional herbal medicinal product used for the temporary relief of symptoms associated with stress, such as fatigue, exhaustion and mild anxiety.**

**This usage is based on traditional use only.**

1

## 2: Before you take this product

**DO NOT TAKE** this product if you are:

- pregnant or breastfeeding
- allergic to any of the ingredients (see section 6)
- under 18 years of age
- suffering from liver or kidney disease

### **Suffering from depression?**

This product is intended for the relief of symptoms associated with stress. If you have symptoms of depression such as persistent low mood you should seek medical advice for appropriate treatment.

## 3: How to take this product

### **Adults and the elderly**

Take 1 tablet twice daily, one before breakfast and one before lunch. Swallow the tablets whole with a glass of water, 30 minutes before food.

Do not take this product for longer than two months.

Do not exceed the stated dose.

### **If you take too much of this product (overdose)**

If you take more than the recommended dose, speak to a doctor, pharmacist or healthcare practitioner and take this leaflet with you.

### **If you forget to take this product**

Do not take twice the dose but continue to take your usual dose at the usual time.

**If you have any questions, or are unsure about anything, please ask your doctor, pharmacist or healthcare practitioner.**

## 4: Side-effects

Like all medicines, this product can have side-effects, although not everybody gets them.

There have been isolated reports of allergic reaction and lowered blood sugar levels in patients taking Rhodiola. However there is no clear relationship between the development of low blood sugar levels and the use of *Rhodiola rosea* extracts.

**Some people may experience side-effects when taking this medicine. If you have any unwanted side-effects you should seek advice from your doctor or pharmacist.**

**In addition, you can help to make sure that medicines remain as safe as possible by reporting any unwanted side-effects via the Internet at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk); alternatively you can call Freephone 0808 100 3352 (available between 10am-2pm Monday-Friday) or fill in a paper form available from your local pharmacy.**

## 5: After taking this product

**You must speak to a healthcare practitioner if your symptoms worsen, if they do not improve after two weeks, or if side-effects not mentioned in this leaflet occur.**

**Do not use your tablets after the expiry date.**

Return any out-of-date tablets to your pharmacist who will dispose of them for you.

The expiry date is printed on the box and the blister pack.

**Store the tablets in a cool dry place.**

**Keep the tablets out of the reach and sight of children.**

**Keep your tablets in the blister pack until it is time to take them.**

## 6: Product description

Each film-coated tablet of this product contains 200mg of extract (as dry extract) from *Rhodiola rosea* L. rhizome and root (1.5-5:1) (WS<sup>®</sup> 1375) (equivalent to 300-1000mg of Rhodiola). Extraction solvent: Ethanol 60% m|m.

**This product also contains the following ingredients:**

Microcrystalline cellulose, croscarmellose sodium, precipitated silicon dioxide, magnesium stearate, hypromellose, stearic acid, iron oxide red (E172), titanium dioxide (E171), anti foam emulsion.

Each pack contains 25, 30, 50, 60, 90, 100 or 120 film-coated tablets. Not all pack sizes may be marketed.

**Registration holder and manufacturer of this product**

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

Traditional herbal registration number: THR 05332/0004

UK distributor:

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

If you would like further information about this product, please contact:

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

Telephone: 01628 488487  
Email: [info@schwabepharma.co.uk](mailto:info@schwabepharma.co.uk)

This leaflet was prepared in June 2008

For a large print, Braille or audio version of this leaflet, call 01628 488487

4

## **LABELLING**

30 tablets of *Rhodiola rosea* root extract 200mg

**Vitano®**

**Vitano®** *Rhodiola rosea*  
root extract 200mg

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.

Active ingredients: Each film-coated tablet of Vitano® contains 200mg of extract (as dry extract) from *Rhodiola rosea* L. rhizome and root (1.5-5:1) (VS® 1375) (equivalent to 300 – 1000mg of *Rhodiola*). Extraction solvent: Ethanol 60% m/m.

Dosage: For oral use.

Adults and the elderly:

Take 1 tablet twice daily, one before breakfast and one before lunch. Swallow the tablets whole with a glass of water, 30 minutes before food.

Warning: Do not exceed the stated dose.

Do not take this product if you:

- are under 18 years of age
- are allergic to any of the ingredients
- are pregnant or breast-feeding
- have kidney or liver problems

Please read the enclosed information leaflet before taking these tablets. Keep out of sight and reach of children.

Store the tablets in a cool dry place

Store in original packaging

Expiry date: see base

THR 05332/0004

Manufactured in Germany.

THR holder: Dr Willmar Schwabe GmbH & Co. KG

Karlsruhe, Germany

UK distributor: Schwabe Pharma (UK) Ltd

Marlow, Bucks SL7 1PD

Telephone: 01628 488487

Email: info@schwabepharma.co.uk



**NEW**

**Vitano®**  
film-coated tablets

*Rhodiola rosea* root extract 200mg

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.

Traditionally used for

- |  |  |
|--|--|
| <input checked="" type="checkbox"/> Stress     | <input checked="" type="checkbox"/> Fatigue      |
| <input checked="" type="checkbox"/> Exhaustion | <input checked="" type="checkbox"/> Mild Anxiety |

30 tablets  
**Vitano®**  
of *Rhodiola rosea* root extract 200mg

**Vitano®**  
of *Rhodiola rosea* root extract 200mg  
30 tablets



30 tablets

Batch No:

Expiry date:

Barcode