

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1 NAME OF THE MEDICINAL PRODUCT

Gruenwalder Travel Ginger Capsules.

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains:

250 mg ginger rhizome (*Zingiber officinale* ROSCOE)

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Hard capsules.

Light blue capsules

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

Traditional herbal medicinal product used to relieve symptoms of travel sickness, based on traditional use only.

#### 4.2 Posology and method of administration

For oral administration.

The capsules should be swallowed whole with 1-2 glasses of water. Do not chew the capsules.

##### **Adults, the elderly and children over 12 years**

2 capsules approximately 30 minutes to one hour before travelling. Do not take more than 8 capsules per day.

##### **Children under 12 years of age**

The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').

##### **Duration of use**

If the symptoms worsen, or persist for more than 5 days, during the use of the product, a doctor or a qualified health care practitioner should be consulted.

### **4.3 Contraindications**

Hypersensitivity to the active substance or any of the excipients  
Peptic or duodenal ulcer.  
Obstruction of the bile duct, cholangitis or gall stones.

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

Do not exceed the stated dose.

Ginger may inhibit platelet aggregation and may decrease platelet thromboxane production thus, theoretically, may increase the risk of bleeding. The product should be discontinued at least 2 weeks prior to elective surgery due to the potential increased risk of bleeding and for potential interactions with medicinal products used during general and regional anaesthesia (see Section 4.5).

The use in children under 12 years age is not recommended due to the lack of adequate data.

If the symptoms worsen, or persist for more than 5 days, during the use of the product, a doctor or a qualified health care practitioner should be consulted.

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

Ginger may increase the risk of bleeding when taken with drugs that affect coagulation and bleeding eg. aspirin, anticoagulants such as warfarin, acenocoumarol, phenindione, apixaban, edoxaban, dabigatran, rivaroxaban, dalteparin, enoxaparin and tinzaparin, phenprocoumon, heparin, antiplatelet drugs such as clopidogrel, and non-steroidal anti-inflammatory drugs such as aspirin, ibuprofen and naproxen..

### **4.6 Fertility, Pregnancy and lactation**

A moderate amount of data on pregnant women (n =490) indicates no malformative or fetoneonatal toxicity of ginger root. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3 'Preclinical safety data').

As a precautionary measure it is preferable to avoid the use during pregnancy. In the absence of sufficient data, the use during lactation is not recommended.

Studies on the effects on fertility have not been performed.

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

No studies on the effect on the ability to drive and use machines have been performed.

In some cases patients have experienced drowsiness while taking ginger. Affected patients should not drive or operate machinery.

#### **4.8 Undesirable effects**

Minor gastrointestinal complaints including stomach upset, heartburn, eructation, bloating, flatulence, nausea, dyspepsia. Frequency common  
Drowsiness has also been reported.

There is one case report of inhibition of platelet aggregation following chronic consumption of large quantities of ginger marmalade. There is one case report of potential interaction with warfarin (see Section 4.5).

If other adverse reactions not mentioned above occur, a doctor or a qualified healthcare practitioner should be consulted.

##### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme website [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

#### **4.9 Overdose**

No cases of overdose have been reported.

Supportive and symptomatic treatment should be provided 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**

Reverse mutation assays (Ames test) on bacteria indicated that the product was not mutagenic in *Salmonella typhimurium* (strains TA 98, TA 100, TA 102, TA 1535 and TA 1537) mutation assays with or without metabolic activation. Adequate tests on reproductive toxicity and carcinogenicity have not been performed.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

#### Capsule excipient

Colloidal anhydrous silica.

#### Capsule shell:

Gelatin

Purified water

Titanium dioxide E 171

Indigo carmine E 132

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

3 years.

### **6.4 Special precautions for storage**

Do not store above 25°C. Store in the original package.

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

PVC/PVDC-Al blister strips in cardboard carton.

Packs of 10, 20 or 50 capsules per package.

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**

Grünwalder Gesundheitsprodukte GmbH  
Ruhlandstr. 5,  
83646 Bad Tölz  
Germany.

**8 MARKETING AUTHORISATION NUMBER(S)**

THR 18457/0023

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

12/06/2018

**10 DATE OF REVISION OF THE TEXT**

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