Puncto Digest capsules
Puncto Travel capsules
Ginger Digest capsules
Ginger Travel capsules

THR 32294/0012
THR 32294/0013
THR 32294/0014
THR 32294/0015

UKPAR

TABLE OF CONTENTS

Lay summary Page 2
Scientific discussion Page 3
Steps taken for assessment Page 12
Summaries of Product Characteristics Page 13
Product Information Leaflets Page 25
Labelling Page 34
PUNCTO DIGEST CAPSULES
PUNCTO TRAVEL CAPSULES
GINGER DIGEST CAPSULES
GINGER TRAVEL CAPSULES

THR 32294/0012-0015

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted PlantaPhile Ltd Traditional Herbal Registration Certificates for the traditional herbal medicinal products Puncto Digest capsules, Puncto Travel capsules, Ginger Digest capsules and Ginger Travel capsules (Traditional Herbal Registration numbers: THR 32294/0012-0015) on 21 November 2011. These medicinal products are available without prescription and can be bought from pharmacies and other outlets.

Puncto Digest capsules and Ginger Digest capsules are traditional herbal medicinal products used for the symptomatic relief of minor digestive complaints such as indigestion, dyspepsia, feelings of fullness, flatulence and temporary loss of appetite, based on traditional use only.

Puncto Travel capsules and Ginger Travel capsules are traditional herbal medicinal product used for the symptomatic relief of travel sickness, based on traditional use only.

Other than the differences in their uses, these medicinal products are identical to each other. The active ingredient in these medicinal products comes from the rhizome of the Ginger plant, which is also known as *Zingiber officinale* ROSCOE.

These registrations are based exclusively upon the longstanding use of Ginger rhizome as a traditional herbal medicine and not upon data generated from clinical trials. There is no requirement under the Traditional Herbal Registration Scheme to prove scientifically that a product works.

No new or unexpected safety concerns arose from these applications and it was, therefore, decided that Traditional Herbal Registration Certificates could be granted.
SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

Introduction ........................................ Page 4
Pharmaceutical assessment ......................... Page 5
Non-clinical assessment ............................... Page 8
Clinical assessment .................................. Page 9
Overall conclusions and risk assessment .......... Page 11
INTRODUCTION

The MHRA granted Traditional Herbal Registration Certificates for the traditional herbal medicines Puncto Digest capsules, Puncto Travel capsules, Ginger Digest capsules and Ginger Travel capsules (THR 32294/0012-0015) to PlantaPhile Ltd on 21 November 2011. These products are on the general sales list (GSL).

These applications were submitted according to Article 16.c of Directive 2001/83 EC, as amended, as part of the Traditional Herbal Medicines Registration Scheme. Puncto Digest capsules and Ginger Digest capsules are used for the symptomatic relief of minor digestive complaints such as indigestion, dyspepsia, feelings of fullness, flatulence and temporary loss of appetite, based on traditional use only, and Puncto Travel capsules and Ginger Travel capsules are used for the symptomatic relief of travel sickness, based on traditional use only.

The data supplied by the applicant demonstrate 30 years of traditional use of Ginger rhizome in the European Community. A satisfactory review of the available safety data on Ginger rhizome has also been provided, together with an Expert Safety Report supporting the proposed products.
**PHARMACEUTICAL ASSESSMENT**

**HERBAL SUBSTANCE:**  
**GINGER RHIZOME**

<table>
<thead>
<tr>
<th>Latin name of plant:</th>
<th>Zingiber officinale Roscoe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common name of plant:</td>
<td>Ginger</td>
</tr>
<tr>
<td>Plant family:</td>
<td>Zingiberaceae</td>
</tr>
</tbody>
</table>

**Manufacture of Herbal Substance**

The Ginger rhizomes are cultivated in Asia, Africa and South America. They are harvested manually after 8 to 9 months growing, after flowering (from April to November/December). Following harvest, the Ginger rhizomes are hand washed, peeled and dried.

The herbal substance is produced and collected in accordance with Good Agricultural and Collection Practice (GACP) guidelines. Pesticides, herbicides, fungicides and fertiliser are used during the production of this herbal substance and during storage the herbal substance may be subjected to CO₂ pressure-treatment or fumigation. It is confirmed that ionising radiation or ethylene oxide is not used.

**Control of Herbal Substance**

An appropriate specification based on the Ph Eur monograph is applied and is acceptable. The specification is supported by the batch data provided.

**Container Closure System**

Satisfactory details of the container closure system are provided and confirmation has been given that all components of the container closure system comply with current regulations relating to plastic materials and articles intended to come into contact with foodstuffs.

**Stability of Herbal Substance**

Confirmation is given that the herbal substance will be tested prior to being used to make the herbal preparation. A shelf-life for the herbal substance is not appropriate because it is only a precursor of the active substance, the herbal preparation. The guideline requires stability testing data for the herbal preparation and the herbal product in the application documents and not for the herbal substance.

**HERBAL PREPARATION:**  
**POWDERED GINGER RHIZOME**

**Manufacture of Herbal Preparation**

A satisfactory description of the manufacturing process of the herbal preparation and flow diagram has been provided. The in-process controls are satisfactorily detailed. The manufacture of the herbal preparation is considered a standard procedure.

Certificates of Analysis for all materials used in the manufacture of the herbal preparation have been provided.
Control of Herbal Preparation
A satisfactory specification with appropriate tests and limits has been provided for the herbal preparation.

Satisfactory analytical procedures are used to control the quality of the herbal preparation. Analytical procedures have been validated, as appropriate.

Certificates of Analysis have been provided for production batches of the herbal preparation, demonstrating satisfactory compliance with the proposed specification.

Container Closure System
Confirmation is provided that all components of the container closure system used to store the herbal preparation comply with current regulations relating to plastic materials and articles intended to come into contact with foodstuffs.

Stability of Herbal Preparation
No stability data are provided. As there is a short time between production of the herbal preparation and it being used to make the herbal product and the herbal preparation is tested prior to being processed into the finished product this is acceptable.

HERBAL PRODUCTS: PUNCTO DIGEST CAPSULES
PUNCTO TRAVEL CAPSULES
GINGER DIGEST CAPSULES
GINGER TRAVEL CAPSULES

Description and Composition of the Herbal Products
The capsules are light blue and hard. Each capsule contains 250 mg Ginger rhizome and the excipients silicon dioxide, gelatin, purified water, titanium dioxide E 171 and indigo carmine E 132.

The compatibility of the herbal preparation with the excipients is demonstrated by the stability testing results. The excipients are controlled in line with their respective Ph Eur monograph, with the exception of indigo carmine E 132, which is controlled in line with a suitable specification. The colorants titanium dioxide E 171 and indigo carmine E 132 also meet the requirements of Commission Directive 95/45/EC (colorants permitted for use in the medicinal products). Satisfactory Certificates of Analysis are provided for all excipients.

The gelatin used to make these capsules is of animal origin. Satisfactory TSE Certificates of Suitability have been provided as evidence of compliance of the gelatine with current requirements.

Manufacture of Herbal Products
A flow diagram outlining the various stages of the manufacturing process and the in-process controls is provided. In-process controls are appropriate considering the nature of the product and the method of manufacture.
**Control of Herbal Products**
The finished product specification is satisfactory. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification.

**Container Closure System**
The capsules are stored in PVC/PVDC-Al blister strips in a cardboard carton. The capsules are available in packs of 10, 20 or 50.

Suitable specifications have been provided by the packaging suppliers and it has been confirmed that all primary packaging materials comply with current regulations.

**Stability of Herbal Products**
Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a product shelf-life of 3 years is appropriate when the storage precautions ‘Do not store above 25° C’ and ‘Store in the original package’ are applied.

**Pharmaceutical Expert**
The Quality Overall Summary has been written by a professional with suitable experience.

**Summaries of Product Characteristics, product labels and Patient Information Leaflets**
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.

**Conclusion**
There are no objections to granting of Traditional Herbal Registrations from a quality point of view.
NON-CLINICAL ASSESSMENT

NON-CLINICAL OVERVIEW
The applicant has submitted a literature review with these applications. An Expert Safety Report was provided, which included reviews of some non-clinical data. The Expert Safety Report was written by a suitably qualified professional.

The overview submitted in support of these applications is satisfactory.

Due to a shortage of published data on Ginger rhizome, it is not possible to assess if the safety package for the phytochemical constituents of this active ingredient 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.

In view of the absence of results of genotoxicity testing, the applicant has provided assurance that results will be provided before the renewal of the registrations.

SUMMARIES OF PRODUCT CHARACTERISTICS (SmPC)
The SmPCs for these products are satisfactory from a non-clinical 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
There are no objections to granting of Traditional Herbal Registrations from a non-clinical point of view.
CLINICAL ASSESSMENT

INDICATIONS
The applicant proposes the following therapeutic indications for Puncto Digest capsules and Ginger Digest capsules:

“Traditional herbal medicinal product used for the symptomatic relief of minor digestive complaints such as indigestion, dyspepsia, feeling of fullness, flatulence and temporary loss of appetite based on traditional use only.”

The applicant proposes the following therapeutic indications for Puncto Travel capsules and Ginger Travel capsules:

“Traditional herbal medicinal product used for the symptomatic relief of travel sickness based on traditional use only.”

These indications are acceptable.

POSOLOGY AND METHOD OF ADMINISTRATION
The applicant has submitted the following instructions for Puncto Digest capsules and Ginger Digest capsules:

“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 of age
One capsule to be taken three times a day at mealtimes.

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 persist for more than 2 weeks during the use of the product, a doctor or a qualified health care practitioner should be consulted.”

The applicant has submitted the following instructions for Puncto Travel capsules and Ginger Travel capsules:

“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 of age
2 capsules with liquid approximately 30 minutes to one hour before travelling. Maximum daily dosage 8 capsules.

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

**EFFICACY**
No clinical efficacy data is required for registration of Traditional Herbal Medicinal Products.

**EVIDENCE OF TRADITIONAL 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 EU.

The applicant has provided a bibliographic review as evidence of the use of Ginger rhizome within the EU for a period exceeding 30 years. The information provided is considered to satisfy the requirement to demonstrate use for at least 30 years of which at least 15 years have been in an EU Member State. The requirements of the Directive are therefore addressed for this aspect.

**SAFETY REVIEW**
Article 16 c 1 (d) requires the applicant to provide a bibliography of the safety data together with an Expert Safety Report.

A safety review has been provided as well as an Expert Safety Report written by a suitably qualified professional.

The safety review and Expert Safety Report are satisfactory.

**PRODUCT LITERATURE**
The SmPCs, PILs and labelling for these products are medically satisfactory.

**CONCLUSION**
There are no objections to granting of Traditional Herbal Registrations from a clinical point of view.
OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY
The quality data submitted with these applications are satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for an application of this type. However the applicant has provided assurance that the results of genotoxicity testing will be provided before the renewal of the registrations.

EFFICACY AND SAFETY
No clinical efficacy data are required for registration of Traditional Herbal Medicinal Products.

The applicant has provided a bibliographic review which shows ample evidence for the use of Ginger rhizome within the EU for a period exceeding 30 years.

A satisfactory review of the safety data has been provided.

The SmPCs, PILs and labelling are satisfactory.

RISK ASSESSMENT
The quality of the products is acceptable and no new non-clinical or clinical safety concerns have been identified. The risk: benefit balance is acceptable and Traditional Herbal Registrations may be granted.
STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the Traditional Herbal Registration applications on 26 February 2010
2. Following standard checks and communication with the applicant the MHRA considered the applications valid on 26 March 2010
3. Following assessment of the applications the MHRA requested further information relating to the clinical dossier on 6 April 2010 and the quality dossier on 26 August 2010
4. The applicant responded to the MHRA’s requests, providing further information on the clinical dossier and quality dossiers on 11 January 2011
5. Following assessment of the response the MHRA requested further information relating to the quality dossier on 6 April 2011
6. The applicant responded to the MHRA’s request, providing further information on the quality dossier on 22 June 2011
7. THR's were granted on 21 November 2011
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Puncto® Digest 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
Capsules, hard.
Light blue capsules.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
Traditional herbal medicinal product used for the symptomatic relief of minor digestive complaints such as indigestion, dyspepsia, feeling of fullness, flatulence and temporary loss of appetite 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 of age
One capsule to be taken three times a day at mealtimes.

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 persist for more than 2 weeks 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).
If the symptoms worsen 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, 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
Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and 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. Frequency 2-3%. 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.

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
Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.
6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Capsule excipient: Silicon dioxide.
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.

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 AUTHORITY HOLDER
PlantaPhile Ltd., 18 Hyde Gardens, Eastbourne, East Sussex, BN21 4PT, UK.

8 MARKETING AUTHORISATION NUMBER(S)
THR 32294/0012

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
21/11/2011

10 DATE OF REVISION OF THE TEXT
21/11/2011
1 NAME OF THE MEDICINAL PRODUCT
Puncto Travel 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
Capsules, hard.
Light blue capsules.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
Traditional herbal medicinal product used for the symptomatic relief 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 of age
2 capsules with liquid approximately 30 minutes to one hour before travelling.
Maximum daily dosage 8 capsules.
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 persist for more than 5 days or worsen 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 data on safety and efficacy. If the symptoms persist for more than 5 days or worsen 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, 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
Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and 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 2-3%. 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.

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
Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.
6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Capsule excipient: Silicon dioxide.
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
PlantaPhile Ltd., 18 Hyde Gardens, Eastbourne, East Sussex, BN21 4PT, UK.

8 MARKETING AUTHORISATION NUMBER(S)
THR 32294/0013

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
21/11/2011

10 DATE OF REVISION OF THE TEXT
21/11/2011
NAME OF THE MEDICINAL PRODUCT
Ginger Digest capsules

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.

PHARMACEUTICAL FORM
Capsules, hard.
Light blue capsules.

CLINICAL PARTICULARS

Therapeutic indications
Traditional herbal medicinal product used for the symptomatic relief of minor digestive complaints such as indigestion, dyspepsia, feeling of fullness, flatulence and temporary loss of appetite based on traditional use only.

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 of age
One capsule to be taken three times a day at mealtimes.
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 persist for more than 2 weeks during the use of the product, a doctor or a qualified health care practitioner should be consulted.

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

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).
If the symptoms worsen 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, 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
Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and 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. Frequency 2-3%.
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.

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
Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS
6.1 **List of excipients**
Capsule excipient: Silicon dioxide.
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.

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**
PlantaPhile Ltd., 18 Hyde Gardens, Eastbourne, East Sussex, BN21 4PT, UK.

8 **MARKETING AUTHORISATION NUMBER(S)**
THR 32294/0014

9 **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**
21/11/2011

10 **DATE OF REVISION OF THE TEXT**
21/11/2011
1 NAME OF THE MEDICINAL PRODUCT
Ginger Travel 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
Capsules, hard.
Light blue capsules.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
Traditional herbal medicinal product used for the symptomatic relief 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 of age
2 capsules with liquid approximately 30 minutes to one hour before travelling.
Maximum daily dosage 8 capsules.
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 persist for more than 5 days or worsen 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 data on safety and efficacy.
If the symptoms persist for more than 5 days or worsen 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, 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
Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and 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 2-3%. 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.

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
Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS
6.1 **List of excipients**  
Capsule excipient: Silicon dioxide.  
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**  
PlantaPhile Ltd., 18 Hyde Gardens, Eastbourne, East Sussex, BN21 4PT, UK.

8 **MARKETING AUTHORISATION NUMBER(S)**  
THR 32294/0015

9 **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**  
21/11/2011

10 **DATE OF REVISION OF THE TEXT**  
21/11/2011
Package Leaflet: Information for The User

Puncto® Digest Capsules
Ginger Rhizome

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without a prescription. However, you still need to take Puncto® Digest carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor or qualified healthcare practitioner if your symptoms worsen or do not improve after 2 weeks.
- If any of the side effects become serious, or you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or qualified healthcare practitioner.

In this leaflet:
1. What Puncto® Digest is and what it is used for
2. Before you take Puncto® Digest
3. How to take Puncto® Digest
4. Possible side effects
5. How to store Puncto® Digest
6. Further information

1. What Puncto® Digest is and what it is used for

Puncto® Digest is a traditional herbal medicinal product used for the symptomatic relief of minor digestive complaints such as indigestion, dyspepsia, feeling of fullness, flatulence and temporary loss of appetite based on traditional use only.

2. Before you take Puncto® Digest

2.1 Do not take Puncto® Digest
- If you are allergic (hypersensitive) to ginger or any of the ingredients in your medicine (see section 6: Further information).
- If you have a peptic or duodenal ulcer.
- If you have any obstruction or any disease of the bile duct or gall stones.
- If you are under 12 years of age.
- If you are pregnant or breast-feeding.

2.2 Take special care with Puncto® Digest
If your symptoms persist for more than two weeks or get worse you must see your doctor or a qualified healthcare practitioner.

You must stop taking this medicine at least 2 weeks before you are planning to have any surgery. Ginger may increase the risk of you bleeding more, or may affect the other medicines given to you during surgery.

2.3 Taking other medicines
Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines. This includes any medicines which you have bought without a prescription.

You must talk to your doctor if you are taking:
- Anti-coagulant (blood thinning) medicines, such as warfarin or heparin.
- Anti-platelet medicines, such as clopidogrel.
- Non-steroidal anti-inflammatory medicines, such as aspirin, ibuprofen or naproxen.

2.4 Pregnancy and breast-feeding
Do not take this product if you are pregnant or breast-feeding because there is no evidence that it is safe to do so.

2.5 Driving and using machines
You may feel drowsy while taking this medicine. If you are affected do not drive or use machines.

3. How to take Puncto® Digest

Remember to always take this medicine with meals and 1-2 glasses of water. The capsules should be swallowed whole and not chewed. Do not exceed the stated dose.

You should check with your doctor, pharmacist or qualified healthcare practitioner if you are not sure.
3.1 How much Puncto® Digest to take

**Adults, the elderly, children over 12 years**
1 capsule three times each day at mealtimes.

**Children under 12 years of age**
Do not give to children under 12 years of age.

3.2 If you take more Puncto® Digest than you should

If you have accidentally taken more than the recommended dosage of Puncto® Digest this usually will not have any side effects. Continue to take the usual dose at the usual time.

If you have accidentally taken a lot of this medicine you may get more side effects or any side effects may get worse. You must talk to your doctor.

3.3 If you forget to take Puncto® Digest

Never take a double dose to make up for a missed dose. Take the next dose at the usual time. Always take with 1-2 glasses of water.

If you have any further questions about taking this medicine, please ask your doctor, pharmacist or qualified healthcare practitioner.

4. Possible side effects

Like all medicines, Puncto® Digest can cause side effects, although not everybody gets them.

**Rare (affects less than 1 in 1,000 people):**
Stomach complaints such as heartburn, burping, wind, feeling full or nausea (feeling sick) may occur.
You may feel drowsy.

Tell your doctor, pharmacist or qualified healthcare practitioner if any of the side effects become serious, or you notice any side effects not listed in this leaflet.

5. How to store Puncto® Digest

Keep out of the reach and the sight of children.

Do not use the capsules after the expiry date on the carton and the blister strip. The expiry date is the last day of that month.

Do not store above 25°C. Keep them in the original package until it is time to take them.

Medicines should not be thrown away in waste water or in household waste. Please ask your pharmacist how to throw away any medicine you do not need anymore. If you do this you will help protect the environment.

6. Further Information

**What Puncto® Digest contains**
The active ingredient in each capsule is: 250 mg ginger rhizome (Zingiber officinale ROSCOE).

The other ingredients are: Colloidal anhydrous silica, gelatin, purified water, titanium dioxide (E171), indigo carmine (E132).

**What Puncto® Digest looks like and contents of the pack**
Puncto® Digest is a light blue capsule. Puncto® Digest comes in blister packs of 10, 20 or 50 capsules. Not all packs may be marketed.

**Traditional Registration Holder and Manufacturer**

Traditional Registration Holder: PlantaPhile Ltd., 18 Hyde Gardens, Eastbourne, East Sussex, BN21 4PT, UK
Tel. +49-172-601-8754

Manufacturer: Grünewald Gesundheitsprodukte GmbH, Ruhlandstr. 5, 83648 Bad Tölz, Germany.

This leaflet was last revised in October 2011.

THR 32294/0012  Certification Mark

For a large print, Braille or audio versions of this leaflet please call +49-172-6018754.

You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Alternatively you can get a paper Yellow Card form from your GP’s surgery or pharmacy, or call free phone 0808 100 3352 (available 10am-2pm Monday - Friday).

© Registered Trade Mark
Package Leaflet: Information for The User

Puncto® Travel Capsules
Ginger Rhizome

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without a prescription. However, you still need to take Puncto® Travel carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor or qualified healthcare practitioner if your symptoms worsen or do not improve after 5 days.
- If any of the side effects become serious, or you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or qualified healthcare practitioner.

In this leaflet:
1. What Puncto® Travel is and what it is used for
2. Before you take Puncto® Travel
3. How to take Puncto® Travel
4. How to store Puncto® Travel
5. Further information

1. What Puncto® Travel is and what it is used for

Puncto® Travel is a traditional herbal medicinal product used to relieve the symptoms of travel sickness based on traditional use only.

2. Before you take Puncto® Travel

2.1 Do not take Puncto® Travel
- If you are allergic (hypersensitive) to ginger or any of the ingredients in your medicine (see section 6: Further information).
- If you have a peptic or duodenal ulcer.
- If you have any obstruction or any disease of the bile duct, or gall stones.
- If you are under 12 years of age.
- If you are pregnant or breast-feeding.

2.2 Take special care with Puncto® Travel

If your symptoms persist for more than 5 days or get worse you must see your doctor, or a qualified healthcare practitioner.

You must stop taking this medicine at least 2 weeks before you are planning to have any surgery. Ginger may increase the risk of you bleeding more, or may affect the other medicines given to you during surgery.

2.3 Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines. This includes any medicines which you have bought without a prescription.

You must talk to your doctor if you are taking:
- Anti-coagulant (blood thinning) medicines, such as warfarin or heparin.
- Anti-platelet medicines, such as clopidogrel.
- Non-steroidal anti-inflammatory medicines, such as aspirin, ibuprofen or naproxen.

2.4 Pregnancy and breast-feeding

Do not take this product if you are pregnant or breast-feeding because there is no evidence that it is safe to do so.

2.5 Driving and using machines

You may feel drowsy while taking this medicine. If you are affected do not drive or use machines.

3. How to take Puncto® Travel

Remember to always take this medicine with 1-2 glasses of water. The capsules should be swallowed whole and not chewed. Do not exceed the stated dose.

You should check with your doctor, pharmacist or qualified healthcare practitioner if you are not sure.
3.1 How much Puncto® Travel to take

Adults, the elderly, 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
Do not give to children under 12 years of age.

3.2 If you take more Puncto® Travel than you should
If you have accidentally taken more than the recommended dosage of Puncto® Travel this usually will not have any side effects. Continue to take the usual dose at the usual time.

If you have accidentally taken a lot of this medicine you may get more side effects or any side effects may get worse. You must talk to your doctor.

3.3 If you forget to take Puncto® Travel
Never take a double dose to make up for a missed dose. Take the next dose at the usual time. Always take with 1-2 glasses of water.

If you have any further questions about taking this medicine, please ask your doctor, pharmacist or qualified healthcare practitioner.

4. Possible side effects
Like all medicines, Puncto® Travel can cause side effects, although not everybody gets them.

Rare (affects less than 1 in 1,000 people):
Stomach complaints such as heartburn, burping, wind, feeling full or nausea (feeling sick) may occur.
You may feel drowsy.

Tell your doctor, pharmacist or qualified healthcare practitioner if any of the side effects become serious, or you notice any side effects not listed in this leaflet.

5. How to store Puncto® Travel
Keep out of the reach and the sight of children.

Do not use the capsules after the expiry date on the carton and the blister strip. The expiry date is the last day of that month.

Do not store above 25°C. Keep them in the original package until it is time to take them.

Medicines should not be thrown away in waste water or in household waste. Please ask your pharmacist how to throw away any medicine you do not need anymore. If you do this you will help protect the environment.

6. Further Information

What Puncto® Travel contains
The active ingredient in each capsule is: 250 mg ginger rhizome (Zingiber officinale ROSC). The other ingredients are: Colloidal anhydrous silica, gelatin, purified water, titanium dioxide (E171), indigo carmine (E132).

What Puncto® Travel looks like and contents of the pack
Puncto® Travel is a light blue capsule. Puncto® Travel comes in blister packs of 10, 20 or 50 capsules. Not all packs may be marketed.

Traditional Registration Holder and Manufacturer

Traditional Registration Holder:
PlantaPhile Ltd., 18 Hyde Gardens,
Eastbourne, East Sussex, BN21 4PT, UK
Tel. +49-172-601-8754

Manufacturer:
Grünewald Gesundheitsprodukte GmbH,
Ruhlandstr. 5, 83646 Bad Tölz, Germany.

This leaflet was last revised in October 2011.

THR 32294/0013 Certification Mark

For a large print, Braille or audio versions of this leaflet please call +49-172-6018754.

You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Alternatively you can get a paper Yellow Card from your GP’s surgery or pharmacy, or call free phone 0808 100 3352 (available 10am-2pm Monday - Friday).
Package Leaflet: Information for The User

Ginger Digest Capsules
Ginger Rhizome

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without a prescription. However, you still need to take Ginger Digest carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor or qualified healthcare practitioner if your symptoms worsen or do not improve after 2 weeks.
- If any of the side effects become serious, or you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or qualified healthcare practitioner.

In this leaflet:

1. What Ginger Digest is and what it is used for
2. Before you take Ginger Digest
3. How to take Ginger Digest
4. Possible side effects
5. How to store Ginger Digest
6. Further information

1. What Ginger Digest is and what it is used for

Ginger Digest is a traditional herbal medicinal product used for the symptomatic relief of minor digestive complaints such as indigestion, dyspepsia, feeling of fullness, flatulence and temporary loss of appetite based on traditional use only.

2. Before you take Ginger Digest

2.1 Do not take Ginger Digest
- If you are allergic (hypersensitive) to ginger or any of the ingredients in your medicine (see section 6: Further information).
- If you have a peptic or duodenal ulcer.
- If you have any obstruction or any disease of the bile duct, or gall stones.
- If you are under 12 years of age.
- If you are pregnant or breast-feeding.

2.2 Take special care with Ginger Digest
If your symptoms persist for more than 2 weeks or get worse you must see your doctor, or a qualified healthcare practitioner.

You must stop taking this medicine at least 2 weeks before you are planning to have any surgery. Ginger may increase the risk of you bleeding more, or may affect the other medicines given to you during surgery.

2.3 Taking other medicines
Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines. This includes any medicines which you have bought without a prescription.

You must talk to your doctor if you are taking:
- Anti-coagulant (blood thinning) medicines, such as warfarin or heparin.
- Anti-platelet medicines, such as clopidogrel.
- Non-steroidal anti-inflammatory medicines, such as aspirin, ibuprofen or naproxen.

2.4 Pregnancy and breast-feeding
Do not take this product if you are pregnant or breast-feeding because there is no evidence that it is safe to do so.

2.5 Driving and using machines
You may feel drowsy while taking this medicine. If you are affected do not drive or use machines.

3. How to take Ginger Digest

Remember to always take this medicine with meals and 1-2 glasses of water. The capsules should be swallowed whole and not chewed. Do not exceed the stated dose.

You should check with your doctor, pharmacist or qualified healthcare practitioner if you are not sure.

Please turn over!
3.1 How much Ginger Digest to take

Adults, the elderly, children over 12 years
1 capsule three times each day at mealtimes.

Children under 12 years of age
Do not give to children under 12 years of age.

3.2 If you take more Ginger Digest than you should
If you have accidentally taken more than the recommended dosage of Ginger Digest this usually will not have any side effects. Continue to take the usual dose at the usual time.

If you have accidentally taken a lot of this medicine you may get more side effects or any side effects may get worse. You must talk to your doctor.

3.3 If you forget to take Ginger Digest
Never take a double dose to make up for a missed dose. Take the next dose at the usual time. Always take with 1-2 glasses of water.

If you have any further questions about taking this medicine, please ask your doctor, pharmacist or qualified healthcare practitioner.

4. Possible side effects

Like all medicines, Ginger Digest can cause side effects, although not everybody gets them.

Rare (affects less than 1 in 1,000 people):
Stomach complaints such as heartburn, burping, wind, feeling full or nausea (feeling sick) may occur.
You may feel drowsy.

Tell your doctor, pharmacist or qualified healthcare practitioner if any of the side effects become serious, or you notice any side effects not listed in this leaflet.

5. How to store Ginger Digest

Keep out of the reach and the sight of children.

Do not use the capsules after the expiry date on the carton and the blister strip. The expiry date is the last day of that month.

Do not store above 25°C. Keep them in the original package until it is time to take them. Medicines should not be thrown away in waste water or in household waste. Please ask your pharmacist how to throw away any medicine you do not need anymore. If you do this you will help protect the environment.

6. Further information

What Ginger Digest contains
The active ingredient in each capsule is: 250 mg ginger rhizome (Zingiber officinale ROSCOE).

The other ingredients are:
Colloidal anhydrous silica, gelatin, purified water, titanium dioxide (E171), indigo carmine (E132).

What Ginger Digest looks like and contents of the pack
Ginger Digest is a light blue capsule. Ginger Digest comes in blister packs of 10, 20 or 50 capsules. Not all packs may be marketed.

Traditional Registration Holder and Manufacturer

Traditional Registration Holder:
PlantaPhile Ltd., 18 Hyde Gardens, Eastbourne, East Sussex, BN21 4PT, UK
Tel. +49-172-601-8754

Manufacturer:
Grünwalder Gesundheitsprodukte GmbH, Ruhlandstr. 5, 83546 Bad Tölz, Germany.

This leaflet was last revised in October 2011.

THR 32294/0014  Certification Mark

For a large print, Braille or audio versions of this leaflet please call +49-172-6018754.

You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Alternatively you can get a paper Yellow Card form from your GP’s surgery or pharmacy, or call free phone 0808 100 3352 (available 10am-2pm Monday - Friday).

® Registered Trade Mark
Ginger Travel Capsules
Ginger Rhizome

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without a prescription. However, you still need to take Ginger Travel carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor or qualified healthcare practitioner if your symptoms worsen or do not improve after 5 days.
- If any of the side effects become serious, or you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or qualified healthcare practitioner.

In this leaflet:
1. What Ginger Travel is and what it is used for
2. Before you take Ginger Travel
3. How to take Ginger Travel
4. Possible side effects
5. How to store Ginger Travel
6. Further information

1. What Ginger Travel is and what it is used for
Ginger Travel is a traditional herbal medicinal product used to relieve the symptoms of travel sickness based on traditional use only.

2. Before you take Ginger Travel
2.1 Do not take Ginger Travel
- If you are allergic (hypersensitive) to ginger or any of the ingredients in your medicine (see section 6. Further information).
- If you have a peptic or duodenal ulcer.
- If you have any obstruction or any disease of the bile duct, or gall stones.
- If you are under 12 years of age.
- If you are pregnant or breast-feeding.

2.2 Take special care with Ginger Travel
If your symptoms persist for more than 5 days or get worse you must see your doctor, or a qualified healthcare practitioner.

You must stop taking this medicine at least 2 weeks before you are planning to have any surgery. Ginger may increase the risk of you bleeding more, or may affect the other medicines given to you during surgery.

2.3 Taking other medicines
Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines. This includes any medicines which you have bought without a prescription.

You must talk to your doctor if you are taking:
- Anti-coagulant (blood thinning) medicines, such as warfarin or heparin.
- Anti-platelet medicines, such as clopidogrel.
- Non-steroidal anti-inflammatory medicines, such as aspirin, ibuprofen or naproxen.

2.4 Pregnancy and breast-feeding
Do not take this product if you are pregnant or breast-feeding because there is no evidence that it is safe to do so.

2.5 Driving and using machines
You may feel drowsy while taking this medicine. If you are affected do not drive or use machines.

3. How to take Ginger Travel
Remember to always take this medicine with 1-2 glasses of water. The capsules should be swallowed whole and not chewed. Do not exceed the stated dose. You should check with your doctor, pharmacist or qualified healthcare practitioner if you are not sure.

Please turn over!
3.1 How much Ginger Travel to take

Adults, the elderly, 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
Do not give to children under 12 years of age.

3.2 If you take more Ginger Travel than you should
If you have accidentally taken more than the recommended dosage of Ginger Travel this usually will not have any side effects. Continue to take the usual dose at the usual time.

If you have accidentally taken a lot of this medicine you may get more side effects or any side effects may get worse. You must talk to your doctor.

3.3 If you forget to take Ginger Travel
Never take a double dose to make up for a missed dose. Take the next dose at the usual time. Always take with 1-2 glasses of water.

If you have any further questions about taking this medicine, please ask your doctor, pharmacist or qualified healthcare practitioner.

4. Possible side effects
Like all medicines, Ginger Travel can cause side effects, although not everybody gets them.

Rare (affects less than 1 in 1,000 people):
Stomach complaints such as heartburn, burping, wind, feeling full or nausea (feeling sick) may occur.
You may feel drowsy.

Tell your doctor, pharmacist or qualified healthcare practitioner if any of the side effects become serious, or you notice any side effects not listed in this leaflet.

5. How to store Ginger Travel
Keep out of the reach and the sight of children.

Do not use the capsules after the expiry date on the carton and the blister strip. The expiry date is the last day of that month.

Do not store above 25°C. Keep them in the original package until it is time to take them.

Medicines should not be thrown away in waste water or in household waste. Please ask your pharmacist how to throw away any medicine you do not need anymore. If you do this you will help protect the environment.

6. Further Information

What Ginger Travel contains
The active ingredient in each capsule is: 250 mg ginger rhizome (Zingiber officinale ROSCOE).

The other ingredients are:
Colloidal anhydrous silica, gelatin, purified water, titanium dioxide (E171), indigo carmine (E132).

What Ginger Travel looks like and contents of the pack
Ginger Travel is is a light blue capsule. Ginger Travel comes in blister packs of 10, 20 or 50 capsules. Not all packs may be marketed.

Traditional Registration Holder and Manufacturer

Traditional Registration Holder:
PlantaPhile Ltd., 18 Hyde Gardens, Eastbourne, East Sussex, BN21 4PT, UK
Tel. +49-172-601-8754

Manufacturer:
Grünewald Gesundheitsprodukte GmbH,
Ruhlandstr. 5, 83846 Bad Tölz, Germany.

This leaflet was last revised in October 2011.

THR 32294/0015 Certification Mark

For a large print, Braille or audio versions of this leaflet please call +49-172-6018754.

You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Alternatively you can get a paper Yellow Card from your GP’s surgery or pharmacy, or call free phone 0803 100 3352 (available 10am-2pm Monday - Friday).

© Registered Trade Mark
Puncto Digest capsules

Blister:

Puncto® Digest
Capsules
Plantaphile Ltd.

Puncto® Digest
Capsules
Plantaphile Ltd.

Puncto® Digest
Capsules
Plantaphile Ltd.

Puncto® Digest
Capsules
Plantaphile Ltd.

Puncto® Digest
Capsules
Plantaphile Ltd.
Carton:

Puncto® Digest Capsules

Ginger rhizome 250mg

A traditional herbal medicinal product used for the symptomatic relief of minor digestive complaints such as indigestion, dyspepsia, feeling of fullness, flatulence and temporary loss of appetite based on traditional use only.

For oral use.
Puncto Travel capsules

Blister:

Puncto® Travel
Capsules
Plantaphile Ltd.

Puncto® Travel
Capsules
Plantaphile Ltd.

Puncto® Travel
Capsules
Plantaphile Ltd.

Puncto® Travel
Capsules
Plantaphile Ltd.

Puncto® Travel
Capsules
Plantaphile Ltd.

Puncto® Travel
Capsules
Plantaphile Ltd.
Ginger Digest capsules

Blister:

Ginger Digest Capsules
Plantaphile Ltd.

Ginger Digest Capsules
Plantaphile Ltd.

Ginger Digest Capsules
Plantaphile Ltd.

Ginger Digest Capsules
Plantaphile Ltd.
Ginger Travel capsules

Blister:

Ginger Travel
Capsules
Plantaphile Ltd.

Ginger Travel
Capsules
Plantaphile Ltd.

Ginger Travel
Capsules
Plantaphile Ltd.

Ginger Travel
Capsules
Plantaphile Ltd.

Ginger Travel
Capsules
Plantaphile Ltd.