Tradimed Ginger capsules

THR 32294/0009

UKPAR

TABLE OF CONTENTS

Lay summary Page 2

Scientific discussion Page 3

Steps taken for assessment Page 12

Summary of product characteristics Page 13

Product information leaflet Page 17

Labelling Page 20
TRADIMED GINGER CAPSULES

THR 32294/0009

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted PlantaPhile Ltd a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Tradimed Ginger capsules (Traditional Herbal Registration number: THR 32294/0009) on 17 November 2011. Tradimed Ginger capsules are available without prescription and can be bought from pharmacies and other outlets.

Tradimed Ginger capsules is a traditional herbal medicinal product used to relieve the symptoms of minor digestive complaints such as indigestion, dyspepsia, feelings of fullness, flatulence and temporary loss of appetite and to relieve symptoms of travel sickness, based on traditional use only. The active ingredient in Tradimed Ginger capsules comes from the rhizome of the Ginger plant, which is also known as Zingiber officinale ROSCOE.

This registration is 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 this application and it was, therefore, decided that a Traditional Herbal Registration Certificate could be granted.
TRADIMED GINGER CAPSULES

THR 32294/0009

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 a Traditional Herbal Registration Certificate for the traditional herbal medicine Tradimed Ginger capsules (THR 32294/0009) to PlantaPhile Ltd on 17 November 2011. This product is on the general sales list (GSL).

This application was submitted according to Article 16.c of Directive 2001/83 EC, as amended, as part of the Traditional Herbal Medicines Registration Scheme. The product is used to relieve the symptoms of minor digestive complaints such as indigestion, dyspepsia, feelings of fullness, flatulence and temporary loss of appetite and to relieve symptoms 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 product.
PHARMACEUTICAL ASSESSMENT

HERBAL SUBSTANCE: GINGER RHIZOME

Latin name of plant:  
Zingiber officinale Roscoe

Common name of plant:  
Ginger

Plant family:  
Zingiberaceae

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
Stability studies have been performed in accordance with current guidelines. The proposed re-test period for the powdered ginger rhizome is acceptable.

HERBAL PRODUCT: TRADIMED GINGER CAPSULES

Description and Composition of Herbal Product
Tradimed Ginger 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 Product
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 Product
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 Product
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.

Summary of Product Characteristics, product labels 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.

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

NON-CLINICAL OVERVIEW
The applicant has submitted a literature review with this application. 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 this application 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 registration.

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The SmPC for this product is 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 a Traditional Herbal Registration from a non-clinical point of view.
CLINICAL ASSESSMENT

INDICATIONS
The applicant proposes the following therapeutic indications:

“Traditional herbal medicinal product used:
- to relieve the symptoms of minor digestive complaints such as indigestion, dyspepsia, feeling of fullness, flatulence and temporary loss of appetite
- to relieve symptoms 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 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
Digestive complaints:
One capsule to be taken three times a day at mealtimes.
Travel sickness:
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
Digestive complaints:
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.
Travel sickness:
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 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 SmPC, PIL and labelling for this product are medically satisfactory.

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

QUALITY
The quality data submitted with this application 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 registration.

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 SmPC, PIL and labelling are satisfactory.

RISK ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The risk: benefit balance is acceptable and a Traditional Herbal Registration may be granted.
TRADIMED GINGER CAPSULES

THR 32294/0009

 Stephens TAKEN FOR ASSESSMENT

1 The MHRA received the Traditional Herbal Registration application on 30 August 2009
2 Following standard checks and communication with the applicant the MHRA considered the application valid on 26 May 2010
3 Following assessment of the application 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 and quality dossiers on 11 January 2011
5 Following assessment of the response the MHRA requested further information relating to the quality dossier on 12 January 2011
6 The applicant responded to the MHRA’s request, providing further information on the quality dossier on 15 March 2011
7 A THR was granted on 17 November 2011
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Tradimed® 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 the symptoms of minor digestive complaints such as indigestion, dyspepsia, feeling of fullness, flatulence and temporary loss of appetite
- 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
Digestive complaints:
One capsule to be taken three times a day at mealtimes.
Travel sickness:
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
Digestive complaints:
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.
Travel sickness:
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.

*Digestive complaints:*
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.

*Travel sickness:*
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
coaulation 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 32294/0009
9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
17 November 2011

10 DATE OF REVISION OF THE TEXT
30 November 2011
Tradimed® Ginger 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 Tradimed® Ginger 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 digestive symptoms worsen or do not improve after 2 weeks.
- You must contact a doctor or qualified healthcare practitioner if your symptoms of travel sickness 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 Tradimed® Ginger is and what it is used for
2. Before you take Tradimed® Ginger
3. How to take Tradimed® Ginger
4. Possible side effects
5. How to store Tradimed® Ginger
6. Further information

1. What Tradimed® Ginger is and what it is used for
Tradimed® Ginger is a traditional herbal medicinal product used
- to relieve the symptoms of minor digestive complaints such as indigestion, dyspepsia, feeling of fullness, flatulence and temporary loss of appetite,
- for symptomatic relief of travel sickness,
based on traditional use only.

2. Before you take Tradimed® Ginger
2.1 Do not take Tradimed® Ginger
- 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 Tradimed® Ginger
If your digestive symptoms persist for more than 2 weeks or get worse you must see your doctor, or a qualified healthcare practitioner. If your symptoms of travel sickness 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.
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.

Please turn over
3. How to take Tradimed® Ginger

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 Tradimed® Ginger to take

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

*Digestive complaints:*
One capsule three times a day at mealtimes.

*Travel sickness:*
2 capsules approximately 30 minutes to one hour before travelling. Do not take more than 6 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 Tradimed® Ginger than you should

If you have accidentally taken more than the recommended dosage of Tradimed® Ginger 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 Tradimed® Ginger

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, Tradimed® Ginger 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 Tradimed® Ginger

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 blister 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 Tradimed® Ginger contains**
The active ingredient in each capsule is: 250 mg ginger rhizome (*Zingiber officinale* ROSEOE). The other ingredients are: Colloidal anhydrous silica, gelatin, purified water, titanium dioxide (E171), indigo carmine (E132).

**What Tradimed® Ginger looks like and contents of the pack**

Tradimed® Ginger is a light blue capsule. Tradimed® Ginger comes in blister packs of 10, 20 or 50 capsules. Not all packs may be marketed.

**Traditional Registration Holder and Manufacturer**

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

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

This leaflet was last revised in October 2011.

THR 32294/0009 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 0803 100 3352 (available 10am-2pm Monday - Friday).
LABELLING

Blister:

Tradimed® Ginger Capsules
Plantaphile Ltd.

Tradimed® Ginger Capsules
Plantaphile Ltd.

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