1.3 Product Information

1.3.1 Summary of Product Characteristics

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Peppermint Water BP 1973

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of oral solution contains 2.5 microlitres of Peppermint oil (*Mentha x piperita* L.

For full list of excipients, see section 6.1

Excipients:

Each 5 ml of oral solution contains 10 mg Nipasept Sodium, comprising; sodium methyl, ethyl and propyl parahydroxybenzoates [E219,E215 and E217]

3. PHARMACEUTICAL FORM

Oral Solution
Clear and colourless

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

A traditional herbal medicinal product used for the symptomatic relief of minor digestive complaints such as dyspepsia, flatulence and stomach cramps, based on traditional use only

4.2. Posology and Method of Administration

Adults and the elderly

Two - eight 5 ml spoonfuls to be taken 3-4 times daily, as required

Children

Over 12 years of age – dose as for adults
Children of 12 years or younger – not recommended

4.3. Contraindications

Hypersensitivity to Peppermint Oil preparations, menthol or any of the excipients

This product contains sodium methyl, ethyl, propyl parahydroxybenzoates [E219, E215 and E217]**.** If you are allergic to parahydroxybenzoates, do not take this product. Refer to Section 2 for content.

The product should not be used in patients with cholangitis, gallstones and any other biliary disorders that require medical supervision and advice.

4.4. Special Warnings and Precautions for Use

Patients who already suffer from gastroesophageal reflux (heartburn) sometimes have an exacerbation of this symptom after taking peppermint oil. Treatment should be discontinued in these patients.

Peppermint oil should be used with caution with inflamed and ulcerated conditions of the gastrointestinal tract.

This product contains sodium methyl, ethyl, propyl parahydroxybenzoates [E219, E215 and E217]**.** and should not be used by patients who are allergic to hydroxybenzoates. Allergic reactions may be delayed in onset.

Use in children under 12 years is not recommended as there is no experience available.

If symptoms worsen during the use of the product, a doctor or a qualified health care practitioner should be consulted.

4.5 Interactions with other Medicinal Products and other forms of Interaction

None reported.

4.6. Pregnancy and Lactation

Because data on the use of Peppermint Water during pregnancy and lactation are not available, its use is not recommended as a general precaution.

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.

4.8. Undesirable Effects

Contact sensitivity to menthol and peppermint oil in patients presenting with intra-oral symptoms in association with burning mouth syndrome, recurrent oral ulceration or a lichenoid reaction have been reported. The frequency is not known.

Allergic reactions to menthol have been reported, with headache, bradycardia, muscle tremor, ataxia, anaphylactic shock and erythematous skin rash. The frequency is not known.

If these or other adverse reactions not mentioned above occur, treatment should be discontinued and a doctor or a qualified healthcare professional consulted.

4.9 Overdose

No case of overdose has been reported with this product.

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

Peppermint oil was negative in two validated tests of genotoxicity, the Ames test and the mouse lymphoma assay.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Glycerol
Nipasept Sodium, comprising sodium methyl, ethyl and propyl parahydroxybenzoates [E219,E215 and E217]
Carbomer
Citric Acid, anhydrous
Purified Water

6.2. Incompatibilities

Not applicable

6.3. Shelf Life

2 years

6.4. Special Precautions for Storage

Keep bottle in outer carton. Keep bottle tightly closed.

6.5. Nature and Contents of Container

100 ml Amber Type III glass bottle with polypropylene screw cap with LDPE liner.

6.6. Special Precautions for Disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER

Viridian Pharma Ltd, Yew Tree House, Hendrew Lane, Llandevaud, Newport, Gwent NP18 2AB

8. MARKETING AUTHORISATION NUMBER

THR20346/0003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23/6/2009

10. DATE OF REVISION OF THE TEXT

23/6/09