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.)

Excipients:

Each 5 ml of oral solution contains 10 mg Nipasept Sodium, comprising; sodium methyl, ethyl and propyl parahydroxybenzoates.

For a full list of excipients, see section 6.1

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, the elderly and children over 12 years of age:

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

This product is not recommended for use in children aged 12 years and under (see 'Section 4.4. Special warnings and precautions for use')

If symptoms worsen, or persist for more than 2 weeks, a doctor or qualified healthcare practitioner should be consulted.

4.3 Contraindications

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

Obstructions of bile ducts, cholangitis, gallstones, and any other biliary diseases.

4.4 Special warnings and precautions for use

Do not exceed the stated dose

Patients who already suffer from gastroesophageal reflux (heartburn) or hiatal hernia 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.

The use in children under 12 years is not recommended as data is not sufficient and medical advice should be sought.

If symptoms worsen, or persist for more than 2 weeks a doctor or a qualified health care practitioner should be consulted.

4.5 Interaction with other medicinal products and other forms of interaction

None reported.

4.6 Fertility, pregnancy and lactation

In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

No studies on the effects on fertility have 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.

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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme website www.mhra.gov.uk/yellowcard.

4.9 Overdose

No case of overdose has been reported with this product.

In the event of an overdose, treatment should be supportive and symptomatic.

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.
Weak and inconsistent genotoxic responses in other non-validated tests are probably toxicologically inconsequential. There is more evidence for genotoxicity potential of menthol and there seems to be a discrepancy between peppermint oil and its most important constituent menthol. However, the present evidence points to a very weak or totally absent genotoxicity of peppermint oil.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Nipasept Sodium, (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

There are no special storage precautions for this product. Store in the original packaging

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

Macarthys Laboratories Limited T/A Martindale Pharma
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8 MARKETING AUTHORISATION NUMBER(S)

THR 01883/0014

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20/06/2017

10 DATE OF REVISION OF THE TEXT

16/10/2018