Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/

Adverse events should also be reported to McNeil Products Limited on freephone 0808 238 9999.

Colpermin IBS Relief Capsules (peppermint oil) Product Information

Presentation:

Sustained release, gastro-resistant capsules containing 0.2mL peppermint oil.

Uses:

Relief of the symptoms of irritable bowel syndrome.

Dosage:

Adults and the elderly: One capsule three times a day. Two capsules three times a day in severe discomfort. Children: There is no experience of use in those under 15 years of age.

Contraindications:

Hypersensitivity to the active substance or to any of the excipients.

Precautions:

Swallow capsule whole. Worsening of symptoms may occur in heart burn sufferers; discontinue treatment in these patients. Do not take if allergic to peanuts or soya. Consult a doctor before use in the following circumstances: first presentation of symptoms for confirmation of IBS, aged 40 years or over and some time since last attack or symptoms have changed, blood passed from the bowel, nausea or vomiting, loss of appetite or weight, paleness and tiredness, severe constipation, fever, recent foreign travel, pregnancy or planned pregnancy, abnormal vaginal bleeding or discharge, difficulty or pain in passing urine. If there are new symptoms or worsening of the condition, or failure to improve over two weeks, the patient should consult their doctor. Do not take immediately after food or with indigestion remedies.

Pregnancy and Lactation:

Should not be used unless the potential benefit to the mother outweighs the possible risks to the developing foetus. It is not known whether peppermint oil or its metabolites are excreted in human milk.

Side effects:

<u>Not known</u>: burning sensation mucosal, anorectal discomfort, dyspepsia, gastroesophageal reflux, nausea, vomiting. Hypersensitivity reactions incl. erythematous rash, headache, bradycardia, muscle tremor and ataxia which may occur when taken with alcohol.

RRP (ex-VAT): 20s: £7.33; 100s: £25.21

Legal category: GSL.

PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe,

Buckinghamshire, HP12 4EG

PL Number(s): PL 15513/0141.

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