Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Colpermin Gastro-resistant Capsules Peppermint oil 0.2ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 0.2ml of peppermint oil.

Excipients: each capsule contains 136 mg Arachis oil, refined (peanut oil).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant Capsules, hard.
Size 1, enteric coated hard gelatin capsule with opaque blue cap, opaque light blue body and a dark blue band between cap and body, containing an oily mixture with an odour of peppermint.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of symptoms of discomfort and of abdominal colic and distension experienced by patients with irritable bowel syndrome.

4.2 Posology and method of administration

Adults and Adolescents 15 years and over:

One capsule three times a day, taken 30-60 minutes before food with a small quantity of water. The capsules should not be taken immediately after food.

The dose may be increased to two capsules, three times a day when discomfort is more severe.

Children under 15 years:

There is no experience of Colpermin Capsules in children under the age of 15 years.

The capsules should be taken until symptoms resolve, usually within one or two weeks. At times when symptoms are more persistent, the capsules can be continued for longer periods of not longer than 2 to 3 months per course.

4.3 Contraindications

This product should not be used in patients who are hypersensitive to any of its ingredients, including menthol and arachis oil (peanut oil).
If you are allergic to peanut or soya, do not use this medicinal product.

4.4 Special warnings and precautions for use

The capsules should not be broken or chewed because this would release the peppermint oil prematurely, possible causing local irritation of the mouth and oesophagus.

Patients who already suffer from heartburn sometimes have an exacerbation of this symptom after taking Colpermin. Treatment should be discontinued in these patients.

Colpermin contains Arachis oil (peanut oil) and should not be taken by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and allergy to Soya, patients with Soya allergy should also avoid Colpermin.

Colpermin should only be used where a clear diagnosis of irritable bowel syndrome has been made by a doctor initially.

The patient should be advised to consult a doctor before use in the following circumstances:

- first presentation of these symptoms for confirmation of IBS
- aged 40 years or over and it is some time since the last attack, or the symptoms have changed
- blood has been passed from the bowel
- there is a feeling of sickness or there is vomiting
- loss of appetite or loss of weight
- paleness and tiredness
- severe constipation
- fever
- recent foreign travel
- pregnancy or planning a pregnancy or possibly pregnant
- 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.

4.5 Interaction with other medicinal products and other forms of interactions

Antacids should not be administered at the same time as Colpermin.

4.6 Fertility, pregnancy and lactation

If you are pregnant, planning a pregnancy, suspect you are pregnant or breast-feeding do not take this medicine before asking your doctor or pharmacist for advice.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Post marketing data:

Adverse drug reactions (ADRs) identified during post-marketing experience with Peppermint Oil are included in the table below. The frequencies are provided according to the following convention:

Very common ≥1/10
Common ≥1/100 and <1/10
Uncommon ≥1/1,000 and <1/100
Rare ≥1/10,000, and <1/1,000
Very rare <1/10,000
Not known (cannot be estimated from the available data)

Adverse Drug Reactions Identified During Post-Marketing Experience with Peppermint Oil Frequency Category Estimated from adequately designed clinical trials or epidemiology studies	
SOC	
Frequency category	*Adverse Event Preferred Term*
Immune System Disorders	

Not known	*Hypersensitivity***
Nervous System Disorders	
Not known	*Burning sensation mucosal*
Gastrointestinal System Disorders	
Not known	*Anorectal discomfort*
Not known	*Dyspepsia*
Not known	*Gastrooesophageal reflux*
Not known	*Nausea*
Not known	*Vomiting*
***Individual intolerance as well as allergic reactions may occur. These may include erythematous skin rash, headache, bradycardia, muscle tremor, ataxia, arthralgia and dry mouth. This may occur in conjunction with alcohol.*	

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

4.9 Overdose

The most commonly reported symptoms of overdose are severe nausea, vomiting, abdominal pain, vertigo, ataxia, drowsiness and coma.

If capsules have been recently ingested, the stomach should be emptied by gastric lavage. Observation should be carried out with symptomatic treatment if necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code A03AX
Antispasmodic and carminative.
The principal pharmacodynamic effect of peppermint oil relevant to the gastrointestinal tract is a dose-related antispasmodic effect on the smooth musculature, due to the interference of menthol with the movement of calcium across the cell membrane. Peppermint oil is slowly released as the matrix passes along the gut, exerting local effects of colonic relaxation.

In vitro studies
In vitro studies show peppermint oil to be effective in relaxing gastrointestinal smooth muscle, possibly through an antagonistic effect on calcium channels in the gut.
Peppermint oil showed antifoaming and carminative activity in *in vitro* studies with observed reductions in gastric and intestinal foam volume.

In vivo studies
Peppermint appears to enhance production of bile. The choleretic and antifoaming effects of peppermint oil play an additional role to the antispasmodic action, in decreasing the symptoms of abdominal distension, discomfort and abdominal pain.

5.2 Pharmacokinetic properties

Enteric-coated Colpermin peppermint oil capsules significantly delayed the menthol metabolite appearance in the urine suggesting that it is released in the colon. In 13 humans, two different enteric-coated peppermint oil capsules led to peak urinary menthol concentrations at three hours and nine hours after oral administration.

5.3 Preclinical safety data

The oral toxicity of menthone was evaluated in an animal model. The decrease in plasma creatinine and the increase in phosphatase alkaline and bilirrubin were dose dependent, after levels of 0, 200, 400 and 800 mg/kg bw/day. The non

observable- effect-level (NOEL) for menthone in this study was lower than 200 mg/kg bw/day. A NOEL of 400 mg/kg bw/day was reported in a 28 day toxicity study in rats.

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

No evidence of carcinogenicity was found for d,l-menthol (major component of peppermint oil) in a 2 year oral dosing study by National cancer institute following dosing of rats and mice up to 7500 ppm and 4000 ppm respectively.
In recent 2 yr gavage studies on pulegone (one of the components of peppermint oil) by NTP, there was no evidence of carcinogenicity in male rats administered 18.75, 37.5, or 75 mg/kg but there was clear evidence of carcinogenic activity of pulegone in female rats. There was also clear evidence of carcinogenic activity of pulegone in male and female mice at 37.5, 75, or 150 mg pulegone/kg bw/d.

However, the study was deemed to have used inappropriate dose levels in excess of the maximum tolerated dose and the relevance of these findings to humans is unknown.

Studies in animals have shown no teratogenic effects.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White beeswax
Arachis oil, refined
Colloidal anhydrous silica

Capsule

Gelatin
Titanium dioxide (E171)
Indigotine (E132)

Enteric coating

Eudragit S100 (methacrylic acid- methylmethacrlate copolymer 1:2)
Eudragit L30 D55 (methacrylic acid- ethylacrylate copolymer 1:1)
Triethyl citrate
Glycerol Monostearate 40-55
Macrogol 4000
Purified Water
Talc

Banding solution

Indigotine (E132)
Gelatin
Purified water

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 container in order to protect from light.

6.5 Nature and contents of container

Pack sizes of 20 or 100 capsules in blister strips of aluminium foil/PVC containing 10 capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Johnson & Johnson (Ireland) Limited
Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0330/034/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 March 1985

Date of last renewal: 08 March 2010

10 DATE OF REVISION OF THE TEXT

June 2021