Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Colpermin IBS Relief Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 0.2ml of Peppermint oil.
Excipient: contains refined arachis oil (peanut oil).
For a full list of excipients, see section see 6.1

3 PHARMACEUTICAL FORM

Gastro-resistant capsules, hard

Product imported from the UK

Enteric coated hard gelatin capsule coloured light blue/dark blue, with a 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 children 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).

4.4 Special warnings and precautions for use

Patients who already suffer from heartburn, sometimes experience an exacerbation of these symptoms when taking the capsule. Treatment should be discontinued in these patients.

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.

This product should not be taken by patients known to be allergic to peanut and / or soya (See section 4.3).

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Fertility, pregnancy and lactation

There are not data available to establish the safety of Colpermin in pregnancy or lactation, therefore, it should be used only if in the opinion of the practitioner, the possible benefits outweigh the possible hazards.

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.*	

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 A03A
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

Beeswax
Refined arachis (peanut) oil
Colloidal silica
Gelatin
Titanium dioxide (E171)
Indigotine (E132)
Eudragit S
Eudragit L
Triethyl citrate
Monostearin
Macrogol 4000
Purified water
Talc
Ammonia

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister strips and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package to protect from light and moisture.

6.5 Nature and contents of container

Over-labelled carton containing 2 blister strips (10 capsules per strip).

Pack size of 20 capsules.

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 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/087/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 6th March 2009

10 DATE OF REVISION OF THE TEXT

April 2014