

PACKAGE INSERT FOR COLPERMIN

SCHEDULING STATUS

To be allocated.

PROPRIETARY NAME AND DOSAGE FORM

COLPERMIN, hard gastro-resistant capsules.

COMPOSITION

Each capsule contains 187 mg (0,2 ml) of *Mentha x piperita* L., *aetheroleum* (peppermint oil).

Excipients:

Capsule content: Beeswax, white; arachis oil (peanut oil), refined; silica, colloidal anhydrous.

Capsule wall: Gelatine; indigotine (E132, indigocarmin), titanium dioxide (E171), methacrylic acid-methyl methacrylate copolymer (1:2), methacrylic acid-ethyl acrylate copolymer (1:1) – dispersion 30%; triethyl citrate, glycerol monostearate 40-55 macrogol 4000.

COLPERMIN capsules contain arachis oil (peanut oil). Refer to “**CONTRAINDICATION**”.

PHARMACOLOGICAL CLASSIFICATION

A 32.2 Other

Class h) Herbal Medicine

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Mechanism of action: The enteric coating delays the release of the peppermint oil until it reaches the distal small bowel, exerting local effects of colonic relaxation.

Pharmacodynamic effects: 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 showed antifoaming and carminative activity *in vitro*. Reductions in gastric and intestinal foam volume were observed in studies with peppermint oil.

In several studies in healthy subjects or patients, who underwent exposure to peppermint oil either by topical intraluminal (stomach or colon) or oral administration by single doses, result in effects, indicating a substantial spasmolytic action of peppermint oil on the smooth muscles of the gastrointestinal tract.

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

Pharmacokinetic properties

Absorption: Menthol and other terpene constituents of peppermint oil are fat soluble and rapidly absorbed at the proximal small intestinal tract.

Distribution: No data on distribution are available.

Biotransformation: Menthol, the main constituent of peppermint oil, is metabolized by glucuronidation. Further investigations are necessary.

Elimination: To some extent, peppermint oil constituents are excreted in the form of glucuronides. The peak menthol urinary excretion levels were lower and secretion delayed with the modified-release preparations such as COLPERMIN than with the immediate release preparations.

INDICATIONS

COLPERMIN is indicated in adults, children above 8 years of age and adolescents for the symptomatic relief of minor spasms of the gastrointestinal tract, flatulence and abdominal pain, especially in patients with irritable bowel syndrome.

CONTRAINDICATIONS

- Hypersensitivity to the active substance, *Mentha x piperita* L., *aetheroleum* (peppermint oil), or to any of the excipients listed under “**COMPOSITION**”.
- Hypersensitivity to arachis oil (peanut oil) or soya.
- Patients with liver disease, cholangitis, achlorhydria, gallstones and any other biliary disorders.

WARNINGS AND SPECIAL PRECAUTIONS

COLPERMIN capsules should be swallowed whole, i.e. not broken or chewed, as this would release the peppermint oil prematurely, possibly causing local irritation of the mouth and oesophagus.

Patients, who already suffer from heartburn or hiatus hernia, have sometimes an exacerbation of this symptom after taking COLPERMIN. Treatment should be discontinued in these patients.

Paediatric population: The use of COLPERMIN is not recommended in children under 8 years of age, as there is no sufficient experience available.

Effects on the ability to drive and use machinery: COLPERMIN has no or negligible influence on the ability to drive and use machines.

INTERACTIONS

No interaction studies have been performed.

Use of food or antacids administered at the same time could cause early release of capsule content.

Medicinal products used to reduce stomach acid, like histamine-2 blockers, proton pump inhibitors or antacids may cause premature dissolution of the enteric coating. Therefore COLPERMIN should be taken at least 2 hours before or after the use of food, antacids or other medicines used to reduce stomach acid.

PREGNANCY AND LACTATION

Pregnancy: The safety of COLPERMIN for use in pregnancy has not been established.

Lactation: It is unknown whether peppermint constituents / metabolites are excreted in human milk. A risk to the newborns / infants cannot be excluded.

COLPERMIN should not be used during breastfeeding, or breastfeeding should be discontinued during treatment with COLPERMIN.

DOSAGE AND DIRECTIONS FOR USE

Adolescents over 12 years of age, adults and older people: 1 to 2 capsules (equivalent to 0,2 to 0,4 ml peppermint oil) up to three times daily.

Children between 8 to 12 years of age: 1 capsule (equivalent to 0,2 ml peppermint oil) up to three times daily.

COLPERMIN capsules must be swallowed whole with sufficient liquid to allow comfortable passage of the capsule. Do not chew, crush or break the capsules. COLPERMIN should be taken at least 2 hours before or after a meal.

The usual duration of the therapy is 1 or 2 weeks. The maximum duration of the therapy is 3 months per course.

Children under 8 years of age: The safety and efficacy of COLPERMIN in children aged under 8 years has not been established.

Special population: No data are available for a dosing instruction in case of impaired renal function.

SIDE EFFECTS

Summary of the safety profile

Hypersensitivity to menthol was reported, with headache, bradycardia, tremor, ataxia, anaphylactic shock, erythematous rash and pruritus. In such cases, COLPERMIN must be discontinued immediately.

Frequent undesirable effects include pyrosis, anorectal discomfort, headache, abnormal smell of faeces, dry mouth, nausea, and vomiting.

Immune system disorders

Less frequent: Hypersensitivity.

Frequency unknown: Anaphylactic shock.

Nervous system disorders

Frequent: Headache.

Frequency unknown: Tremor, ataxia.

Eye disorders

Less frequent: Blurred vision.

Cardiac disorders

Frequent unknown: Bradycardia.

Gastrointestinal disorders

Frequent: Pyrosis, nausea, vomiting, anorectal discomfort, dry mouth, abnormal smell of faeces.

Less frequent: Gastric haemorrhage.

Frequency unknown: Perianal pain, diarrhoea.

Skin and subcutaneous tissue disorders

Less frequent: Pruritis.

Frequency unknown: Erythematous rash.

Renal and urinary disorders

Frequency unknown: Dysuria, inflammation of the glans of the penis, urine odour abnormal.

Paediatric population

There is only limited safety experience with the use of COLPERMIN in the paediatric population. It is expected that the possible adverse reactions in the paediatric population are the same as for adults.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Symptoms

Overdose may cause severe gastrointestinal symptoms, diarrhoea, rectal ulceration, epileptic convulsions, loss of consciousness, apnoea, nausea, a disturbance in cardiac rhythms, ataxia and other CNS problems, probably due to the presence of menthol.

Management

In the event of overdose, the stomach should be emptied by gastric lavage. Observation should be carried out with symptomatic treatment if necessary.

IDENTIFICATION

Gastro-resistant hard capsule.

Body opaque light blue / cap opaque dark blue with a blue band between body and cap. Capsule size 1 (19,4 mm x 6,8 mm).

PRESENTATION

COLPERMIN is available in PVC / aluminium blister strips, each containing ten hard capsules.

The blister strips are packed in cartons containing 30 capsules (3 blister strips).

STORAGE INSTRUCTIONS

Store at or below 25 °C. Store in the original package to protect from light and moisture.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

REGISTRATION NUMBER

To be allocated by Council upon registration.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Equity Pharmaceuticals (Pty) Ltd.
100 Sovereign Drive
Route 21 Corporate Park
Nellmapius Drive
Irene

DATE OF PUBLICATION OF THE PACKAGE INSERT

To be allocated by Council upon registration.

This medicine has not been evaluated by the MCC. This medicine is not intended to diagnose, treat, cure or prevent any disease.

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