

**Patient leaflet in accordance with the Pharmacists' Regulations
(Preparations) - 1986**

This medicine is dispensed without a doctor's prescription

Colpermin capsules

Active ingredient: Peppermint oil 187 mg

For inactive ingredients and allergens in the medicine: see section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine.

This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

You should take the medicine according to the instructions provided in the dose section of this leaflet. Consult the pharmacist if you need further information. Contact the doctor if the disease symptoms worsen or do not improve usually after 2 weeks.

1. What is this medicine intended for?

Colpermin is used to treat symptoms of discomfort, abdominal pain and bloating due to irritable bowel syndrome.

Therapeutic group: Gastrointestinal products

The active ingredient of Colpermin is natural peppermint oil extracted from the above-ground parts of the *Mentha Piperita* L. (peppermint). Colpermin capsules contain peppermint oil, the main ingredient of which is menthol. In order to enable local action of peppermint oil in the bowel, each capsule is coated with a gastric acid resistant protective film, which prevents premature release of peppermint oil in the stomach.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient peppermint oil, menthol, peanuts and soya (possible cross-sensitivity) or to any of the other ingredients in this medicine (see the list of excipients in section 6: "Additional information").
- you suffer from bile duct obstruction, gallbladder inflammation or liver impairment.

Special warnings about using this medicine

Before using Colpermin, tell your doctor if:

- you suffer from deficiency of hydrochloric acid in the stomach, heartburn (which may be also caused by diaphragmatic hernia). In such cases, the symptoms may be exacerbated following peppermint oil use.

Children and adolescents

This medicine is intended for use in adults and adolescents aged 15 years and over.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Particularly if you are taking:

- Antacids. This could cause the capsule to dissolve prematurely and the leaking peppermint oil to cause heartburn.

Pregnancy and breastfeeding

There is no sufficient data about the use in pregnant women and effects in the fetus. Systematic scientific studies have never been conducted. It is not known whether peppermint ingredients are secreted into breast milk. Do not use the medicine during pregnancy and during breastfeeding, unless there is an established need to do so.

Important information about some of this medicine's ingredients

Colpermin contains peanut oil (Arachis oil). If you are sensitive to peanuts or soya, do not use the medicine.

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The standard dose is usually:

Adults and elderly patients:

One capsule 3 times daily, in cases of severe symptoms, the dose may be increased to 2 capsules 3 times daily (equivalent to 0.6 – 1.2 mL peppermint oil).

Adolescents aged 15 to 17 years:

One capsule 3 times daily (equivalent to 0.6 mL peppermint oil).

Take the capsules whole at least 2 hours before or after a meal with some fluid.

Do not exceed the recommended dose.

If you think the effect of the medicine is too weak or too strong, please talk to the doctor or pharmacist.

- Use the medicine until the symptoms are relieved, usually for a period of 1 to 2 weeks and no longer than 3 months. Please notify the doctor or pharmacist if the symptoms are not relieved within this period.

- Do not break or chew the capsules, otherwise the peppermint oil released from them may cause symptoms of irritation, especially heartburn.

If you have accidentally taken a higher dose, immediately contact a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. In any case, do not induce vomiting and do not consume milk or alcohol.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Colpermin may cause side effects in some users. Do not be alarmed by this list of side effects. You may not suffer from any of them.

Stop taking this medicine and seek medical advice immediately if you experience heart rate slowing, reddish skin rash, urethral irritation, and when taken at the same time with alcohol: tremor and impaired coordination. In all these cases, the reactions observed were temporary. These effects are very rare.

Please follow the guidelines for overdose cases in section 3.

Common side effects:

Heartburn, local irritation in the area of the anus, nausea, vomiting and headache.

Uncommon side effects:

Blurred vision, gastric bleeding, itching, allergic reactions accompanied by skin rash and anaphylactic shock.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting side effects following drug treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

- Do not use the medicine after the expiry date (exp. date) that appears on the carton package. The expiry date refers to the last day of that month.

Storage conditions

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

6. Additional information**In addition to the active ingredient, this medicine also contains:**

Arachis oil, gelatin, white beeswax, methacrylic acid-ethylacrylate copolymer (1:1), triethyl citrate, water, colloidal anhydrous silica, methacrylic acid- methyl methacrylate copolymer (1:2), titanium dioxide, glycerol monostearate 40-55, talc, micronized, macrogol 4000, indigotine (E132).

What the medicine looks like and contents of the pack:

The pack contains 20/30/50/100 capsules. Not all pack sizes may be marketed.

Manufacturer's name and address: Tillotts Pharma AG, Rheinfelden, Switzerland

Registration holder's name and address: Tradis Gat Ltd., 32 Shacham St., Petach Tikva 4951727

This leaflet was revised in December 2023 according to MOHs guidelines

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1090726971