

Information for the patient

Please read this package leaflet carefully. It contains important information. This medicine has either been prescribed to you personally by your doctor or you have obtained it from a pharmacy or drugstore without a medical prescription. In order to derive the greatest benefit from it, you should use the medicine as described in the package leaflet or as directed by your doctor, pharmacist or druggist. Please keep this package leaflet; you may wish to read it again later on.

Colpermin®

Herbal medicine

What is Colpermin® and how is it used?

The active constituent of Colpermin is natural peppermint oil, which is obtained from the above-ground parts of *Mentha piperita* L. (peppermint). Colpermin capsules contain peppermint oil, with its main constituent, menthol, embedded in a paste-like base. Colpermin is used symptomatically for hyperirritability of the bowel, especially of the large bowel (irritable colon), and for bowel spasm, particularly large-bowel spasm, as well as a sensation of fullness and bloating. To allow the peppermint oil to take effect locally in the bowel, each capsule is coated with a gastro-resistant protective film, which prevents premature release of the peppermint oil within the stomach.

What else should be noted?

If possible, the medicine should not be taken at the same time as food or medicines for heartburn. Otherwise, this could cause the capsule to dissolve prematurely and the leaking peppermint oil to cause heartburn. In addition to medicinal treatment of irritable bowel symptoms, dietary adjustments are often beneficial. Please ask your doctor or pharmacist.

When should Colpermin® not be used or should be used with caution?

Colpermin should not be administered to children below 8 years of age or to patients with a body weight below 20 kg. Colpermin contains peanut oil. It should not be taken if you are hypersensitive (allergic) to peanut and soy. Colpermin should not be used in cases of known hypersensitivity to peppermint oil, menthol or to any of the excipients listed in the composition. Colpermin should not be used in cases of bile duct obstruction, gallbladder inflammation or liver damage.

Avoid taking this product at the same time as with medicine for heartburn or in cases of hydrochloric acid deficiency in the stomach. If you suffer from heartburn (including when it is caused by a diaphragmatic hernia), your symptoms sometimes get worse after taking peppermint oil. In that case you should stop taking this medicine. Please tell your doctor or pharmacist or druggist if you

- have any other illnesses
- have allergies or
- are taking other medicines (including over-the-counter ones!).

May Colpermin® be taken during pregnancy or breastfeeding?

Based on previous experience, no risk in children have been identified when used as directed. However, no systematic scientific studies have ever been conducted. It is unknown if peppermint constituents are excreted in human breast milk. As a precaution, you should avoid medication during pregnancy and breastfeeding if possible or ask your doctor, pharmacist or druggist for advice.

How do you use Colpermin®?

Adults 18 years or older:

Unless otherwise prescribed by your doctor, 3 x 1 capsule (for severe symptoms, 3 x 2 capsules) a day.

Adolescents between 12 and 17 years of age:

3 x 1 capsule a day

Children above 8 years of age with a body weight above 20 kg:

2 x 1 capsule a day

Children under 8 years of age should not take Colpermin.

The capsules should be taken whole, with a small amount of liquid, at least 2 hours before or after a meal.

The medication should be continued until your symptoms have disappeared.

This is normally the case within 1-2 weeks. Treatment may be continued for a maximum of 3 months. Please inform your doctor or pharmacist if the symptoms do not subside within the stated time.

The capsules should not be broken or chewed; otherwise, the released peppermint oil may produce symptoms of irritation, especially heartburn. Keep to the dosage given in the package leaflet or prescribed by your doctor.

Please talk to your doctor, pharmacist or druggist if you think that the medicine is having too weak or too strong an effect.

What side effects can Colpermin® have?

The following side effects could occur with the ingestion or use of Colpermin:

Common (affects 1 to 10 in 100 patients)

heartburn, local irritation around the anus (perianal irritation) or nausea, vomiting as well as headache.

Uncommon (affects 1 to 10 in 1000 patients)

allergic reactions with skin rash and possibly anaphylactic shock, itching, stomach bleeding or blurred vision.

Very rare (affects less than 1 in 10 000 patients)

slowed heartbeat, exanthematous skin rash, irritation of the urethra, and, when taken at the same time as alcohol, tremor and impaired coordination. In such circumstances, as well as in case of an overdose, the medicine should be discontinued immediately, and medical advice should be sought without delay. Under no circumstances induce vomiting or consume milk or alcohol in case of an overdose. Please inform your doctor, pharmacist or druggist, if you notice any side effects that are not described here. This applies in particular to side effects not specified in this leaflet.

What else should be noted?

Shelf life

Do not use this medicine after the expiry date ("EXP") stated on the container.

Storage instruction

Do not store above 25 °C.

Store in the original packaging.

Store the container in the outer carton in order to protect the contents from light and moisture. Keep out of the reach of children.

Other information

Remove the capsules carefully from the blisters. Your doctor, pharmacist or druggist can give you more information. These individuals possess the comprehensive Information for healthcare professionals.

What does Colpermin® contain?

One gastro-resistant hard gelatine capsule contains:

Active substances

0.2 mL (= 187 mg) peppermint oil (*Mentha x piperita* L., aetheroleum).

Excipients

Capsule content: Beeswax, bleached, peanut oil (136 mg), refined, highly dispersed silica
Capsule shell: gelatine, indigotine (E132), 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, talc, water.

License number

45214 (Swissmedic)

Where can you get Colpermin®? What packs are available?

In drugstores and pharmacies without a medical prescription (D).
Packs of 30 and 100 capsules.

Marketing authorisation holder

Tillotts Pharma AG, 4310 Rheinfelden, Switzerland.

Manufacturer

Tillotts Pharma AG, 4417 Ziefen, Switzerland.

This package leaflet was last reviewed by the Swiss Agency for Therapeutic Products (Swissmedic) in January 2024.