

Patient information

Information for Patients

Please read this package leaflet carefully, because it contains important information. This medicinal product has either been prescribed for you personally by your doctor or you have obtained it without a medical prescription from a pharmacy. In order to gain the most benefit from it, you should use the medicinal product as stated in the package leaflet or as directed by your doctor or pharmacist. Please retain the 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 overground parts of *Mentha Piperita* L (peppermint). Colpermin capsules contain peppermint oil, with its chief constituent, menthol, embedded in a paste-like base. Colpermin has a relaxing, antispasmodic effect on the bowel muscles in hyperirritability of the bowel, especially of the large bowel (irritable colon), and in bowel spasm, particularly large-bowel spasm. The relaxing effect of peppermint oil prevents unpleasant sensation of fullness and bloating, and facilitates the passing of bowel gases. Accompanying cramp-like pains are thus relieved. In order for the peppermint oil to be able to take effect locally in the bowel, each capsule is coated with a gastric acid-resistant protective film, which prevents premature release of the peppermint oil in the stomach.

Colpermin is intended for the relief of symptoms of irritable bowel syndrome.

What else should be noted?

If possible, the medicinal product should not be taken at the same time as food or products for heartburn. Otherwise, this could cause the capsule to dissolve prematurely and the leaking peppermint oil to produce heartburn.

In addition to the drug-based treatment of irritable bowel symptoms, dietary adjustments are often beneficial. Please ask your doctor or pharmacist.

There is little experience in children below 15 years of age, so Colpermin should be administered to such patients only if expressly prescribed by a doctor.

When must Colpermin® not be used at all or only with caution?

Colpermin must not be used in cases of known hypersensitivity to peppermint oil, especially 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. In adolescents or children under 15 years of age, Colpermin should be administered only if expressly prescribed by a doctor.

Administration at the same time as products for heartburn or when there is a deficiency of hydrochloric acid in the stomach should be avoided.

Please tell your doctor or pharmacist if you

- have any other illnesses
- have allergies
- are taking other medicinal products (including over-the-counter ones).

Please consult a doctor before use if it is the first presentation of symptoms for confirmation of irritable bowel syndrome.

May Colpermin® be taken/used during pregnancy or breast-feeding?

Experience to date shows that there is no known risk to the child when used as directed. However, no systematic scientific studies have ever been conducted. As a precaution, you should as far as possible avoid taking any medicinal products during pregnancy and breast-feeding or seek advice from your doctor or pharmacist.

How do you use Colpermin®?

Adult, adolescents aged 15 and above.

Unless otherwise prescribed by your doctor, one capsule three times a day, ½ to 1 hour before meals on an empty stomach, with a little liquid. This dosage may be increased to two capsules three times a day if discomfort is severe. The medication should be continued until the symptoms have disappeared. This is normally the case within 1-2 weeks. Please inform your doctor or pharmacist if the symptoms do not subside within the stated time.

The capsule should not be broken or chewed, otherwise peppermint oil released could produce symptoms of irritation, especially heartburn. Keep to the dosage given in the package leaflet or prescribed by your doctor. If you think that the medicinal product is having too weak or too strong an effect, please talk to your doctor or pharmacist.

What side effects can Colpermin® have?

The following side effects could occur with the ingestion or use of Colpermin: heartburn might arise if taken on a full stomach or by patients with gastric acid deficiency. In patients with haemorrhoids, local irritation (peri-anal irritation) may occur during treatment with Colpermin. In very rare cases, patients may experience an allergic reaction to the active constituent or its main component, menthol. Other very rare side effects that have been reported are headache, a slowing down of the heart beat, and, when taken at the same time as alcohol, tremor and impaired co-ordination of movements. In all cases, however, the reactions observed were temporary and harmless. In such circumstances, the medicinal product should be discontinued immediately, and medical advice sought without delay.

If you notice any side effects not described here, please inform your doctor or pharmacist.

What else should be noted?

Remove the capsules from the blisters carefully. Keep the medicinal product out of reach of children. Colpermin should be stored below 25°C and kept out of direct sunlight (preferably in the original packaging). Do not use the medicinal product after the date marked "EXP". You can obtain further information from your doctor or pharmacist. These people have detailed prescribing information available to them.

What does Colpermin® contain?

One gastric acid-resistant hard gelatine capsule contains 0.2ml peppermint oil (187mg). This product also contains excipients: white beeswax, Arachis Oil, Colloidal Silica (Aerosil 200), methacrylic acid-Methyl methacrylate(1:2), Methacrylic acid-Ethyl-acrylate(1:1) dispersion(30%), Triethyl citrate, Glyceryl monostearate 40-55 Monostearin, Macrogol 4000, Talc; and the dye indigotin (E 132).

Overdose

In the event of an overdose, please seek immediate medical attention.

Where do you obtain Colpermin®? What pack sizes are available?

From pharmacies without a medical prescription. Packs of 20's capsules.

Marketing authorization holder

Wellchem Pharmaceuticals (Pte). Ltd.

221 Henderson Road, #04-15 Henderson B Building, Singapore 159557

Tel: 6276 6533 Fax: 6276 5672

Email: wellchem@singnet.com.sg

Manufacturer

Tillotts Pharma AG, 4417 Ziefen, Switzerland.

This package leaflet was last checked in October 2004 by H.S.A. Singapore