



## **Information for the patient**

Please read this package leaflet carefully because it contains important information.

This medicine 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 medicine as stated in the package leaflet or as directed by your doctor or pharmacist.

Please keep the package leaflet, you may wish to read it again later on.

## **Colpermin<sup>®</sup>**

### **What is Colpermin<sup>®</sup> 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 gastric acid-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 heartburn remedies. Otherwise, this could cause the capsule to dissolve prematurely and the leaking peppermint oil to produce heartburn.

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

### **When must Colpermin<sup>®</sup> not be used at all?**

Colpermin must not be administered to children below 8 years of age.

### **When must Colpermin® should be used with caution?**

Colpermin must not be used in cases of known hypersensitivity to peppermint oil, menthol, peanuts and soya (cross-allergy possible) 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 heartburn remedies 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 if you

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

### **May Colpermin® be taken during pregnancy or breastfeeding?**

Adequate data on its use in pregnant women and the effects on the unborn child do not exist. No systematic scientific studies have ever been conducted. It is unknown if peppermint constituents are excreted in human breast milk. This medicinal product must not be used during pregnancy or while breastfeeding unless this is clearly necessary.

### **How do you use Colpermin®?**

Adults, elderly patients:

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 must 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 the 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 or pharmacist if you think that the medicine is having too weak or too strong an effect.

### **What side effects may Colpermin® have?**

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

Common side effects are heartburn and local irritation around the anus (perianal irritation) as well as nausea, vomiting and headache. Uncommon side effects are allergic reactions with skin rash and possibly anaphylactic shock, itching, stomach bleeding or blurred vision. Other very rare side effects include 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 or pharmacist if you notice any side effects that are not described here.

### **What else should be noted?**

Remove the capsules carefully from the blisters.

Do not use this medicine after the expiry date, which is stated on the carton after "EXP".

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

Keep this medicine out of the reach of children.

### **What does Colpermin® contain?**

One gastric acid-resistant hard gelatine capsule contains 0.2 mL peppermint oil (187 mg).

This product also contains excipients and the colouring agent indigotine (E 132) as well as peanut oil (arachis oil).

### **License number**

TT50-4508

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

From pharmacies without a medical prescription.

Packs of 20 capsules.

**Marketing Authorisation Holder**

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Mangere 2022

New Zealand

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