COLPERMIN®

Active ingredient: peppermint oil

Consumer Medicine Information (CMI)

This leaflet provides important information about taking COLPERMIN. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using COLPERMIN.

Where to find information in this leaflet:

- 1. Why am I taking COLPERMIN?
- 2. What should I know before I take COLPERMIN?
- 3. What if I am taking other medicines?
- 4. How do I take COLPERMIN?
- 5. What should I know while taking COLPERMIN?
- 6. Are there any side effects?
- 7. Product details

1. Why am I taking COLPERMIN?

COLPERMIN contains the active ingredient peppermint

oil. Peppermint oil is a natural ingredient extracted from the peppermint plant (*Mentha piperita L.*). To allow the peppermint oil to take effect locally in the bowel, each modified release capsule is coated with a gastric acidresistant protective film, which prevents premature release of the peppermint oil within the stomach.

COLPERMIN is used for the symptomatic relief of bowel spasms, cramps, bloating and abdominal pain, especially in patients with irritable bowel syndrome.

2. What should I know before I take COLPERMIN?

Warnings

Do not use COLPERMIN:

- if you are allergic to peppermint oil, menthol, peanuts and soya or to any of the excipients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.
- if you have gallstones or any other disorders of the biliary system including inflammation of the bile duct (cholangitis)
- if you have liver disease or liver damage
- if you suffer from low production of gastric acid in the stomach (a condition called achlorhydria)
- for a child aged below 8 years of age.

Check with your doctor or pharmacist if you:

- suffer from heartburn, including heartburn due to a hiatus hernia, where part of your stomach protrudes upwards into your chest (your symptoms may become worse if you take COLPERMIN)
- have any other medical conditions
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant. COLPERMIN must not be used during pregnancy or if you are of childbearing age and not using contraception. There is no information about the use of COLPERMIN in pregnant women and its effect on the unborn child.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed. COLPERMIN must not be used when breastfeeding. It is not known if the constituents in peppermint oil pass into human breast milk.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with COLPERMIN and affect how it works and increase the risk of side effects.

These include:

 antacids and other heartburn remedies such as medicines that reduce stomach acids (e.g. histamine-2 blockers and proton pump inhibitors).

COLPERMIN should be taken at least 2 hours before or after these medicines.

Taking antacids and other heartburn remedies at the same time as COLPERMIN could cause the capsule to dissolve before it should and the leaking peppermint oil to produce heartburn.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect COLPERMIN.

4. How do I take COLPERMIN?

How much to take

Adults

Take one capsule three times a day. The dose can be increased to two capsules three times a day if required for severe symptoms.

Adolescents between 12 and 17 years of age

Take one capsule three times a day.

Children between 8 and 11 years of age (weighing above 20 kg)

Take one capsule twice a day.

Children under 8 years of age

Children under 8 years of age must not take COLPERMIN.

COLPERMIN® 1

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

When to take COLPERMIN

- Swallow the capsules whole with a full glass of water, at least 2 hours before or after a meal
- The capsules should not be broken or chewed otherwise the peppermint oil inside may irritate your stomach and it may cause heartburn
- The capsules should be taken at least 2 hours before or after antacids and other heartburn remedies (see Section 3. What if I am taking other medicines?).

How long to take COLPERMIN

Keep taking the capsules until the symptoms have disappeared. This may take 1-2 weeks.

If your symptoms persist after 2 weeks, tell your doctor or pharmacist. This medicine can be used for up to 3 months.

If you forget to take COLPERMIN

If you miss your dose at the usual time, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you take too much COLPERMIN

If you think that you have used too much COLPERMIN, you may need urgent medical attention.

You should immediately:

- phone the National Poisons Centre on 0800 POISON (0800 764 766), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. WHAT SHOULD I KNOW WHILE TAKING COLPERMIN?

Things you should do

As well as using COLPERMIN to treat your irritable bowel symptoms, changes to your diet may also be helpful. Speak to your doctor or pharmacist.

Remind any doctor, dentist or pharmacist you visit that you are using COLPERMIN.

Stop taking COLPERMIN and tell your doctor or pharmacist if:

- you have symptoms of heartburn
- your symptoms have not gone away after 2 weeks or get worse.

Things you should not do

 Do not break or chew the capsules, as this could release the peppermint oil into your stomach instead of your bowel.

Driving or using machines

This medicine is not expected to affect your ability to drive or use machines or tools.

Drinking alcohol

Trembling and impaired coordination have been seen in patients when taking COLPERMIN at the same as alcohol.

Looking after COLPERMIN

- Store at or below 25°C
- Keep the capsules in their original packaging to protect them from light and moisture.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

- If your doctor or pharmacist tells you to stop taking this medicine
- If the expiry date has passed
- The packaging is torn or shows signs of tampering.

Getting rid of any unwanted medicine

Ask your pharmacist what to do with any medicine that is left over.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Less serious side effects	What to do
Digestive system:	Stop taking COLPERMIN and speak to your doctor or pharmacist if you have any of
General body: • headache	these less serious side effects and
Genitals: • inflamed head of the penis	they worry you.
Nervous system: • trembling, shaking, movement and balance problems (when taking with alcohol)	
Urinary system:problems and/or pain when passing urine	

COLPERMIN® 2

Tests requested by your doctor:
 low levels of white blood cells

Serious side effects

Serious side effects	What to do
Digestive system: • stomach pain, vomiting blood or material that looks like coffee grounds and blood in the stools which might be signs of bleeding in the stomach	Stop taking COLPERMIN and call your doctor straight away or go straight to the Emergency
Eyes: • blurred vision	Department at your nearest
Heart: • slowed heartbeat	hospital if you notice any of these serious
 Hypersensitivity (allergic) reaction: shortness of breath, wheezing or problems breathing swelling of the face, lips, tongue or other parts of the body rash, itching, hives on the skin sudden severe allergic reaction with signs like drop in blood pressure and breathing problems (anaphylactic shock) 	side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to Medsafe online at https://pophealth.my.site.com/carmreportnz/s/. By reporting side effects, you can help provide more information on the safety of this medicine.

7. PRODUCT DETAILS

This medicine is available without a doctor's prescription.

What COLPERMIN contains

Active ingredient (main ingredient)	Peppermint oil 187 mg (0.2 mL)
Other ingredients (inactive ingredients)	Capsule content:
Potential allergens	Contains peanut oil (arachis oil)

Do not take this medicine if you are allergic to any of these ingredients.

What COLPERMIN looks like

COLPERMIN modified release capsules have an opaque light blue body, opaque blue cap and a dark blue band between body and cap.

COLPERMIN is packed in PVC/aluminium blister strips in a pack containing 20 capsules.

Other pack sizes are not currently available.

Who supplies COLPERMIN

Chiesi New Zealand Ltd Suite 1, 470 Parnell Road Parnell

Auckland 1052

Email: medinfo.au@chiesi.com
Website: www.chiesi.com.au

Manufactured by Tillotts Pharma AG, Switzerland.

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COLPERMIN® 3