

COLPERMIN[®]

GASTRO-RESISTANT CAPSULES
PEPPERMINT OIL 0.2ml

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However you still need to take Colpermin carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Treatment should not be commenced without a prior diagnosis of Irritable Bowel Syndrome by your doctor.
- Speak to your doctor or pharmacist if you suffer from any of the conditions mentioned in Section 2 or if you are taking any other medicines. (See Section 2)
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 2 weeks.
- If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please contact your doctor or pharmacist.

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1 What Colpermin is and what it is used for

Colpermin is an antispasmodic which is used to relieve the bloating, painful spasms and cramps which occur in the large bowel in Irritable Bowel Syndrome (IBS). The capsules contain peppermint oil, which relaxes the spasm of the bowel wall. This relieves pain and allows pockets of gas, which may have made you feel bloated, to pass along the bowel and out of the body.

Irritable Bowel Syndrome is a condition in which there is pain, spasm and bloating at almost any point between the groin, the navel and the sides, sometimes accompanied by diarrhoea and constipation. The symptoms may be more noticeable when you are feeling stressed and anxious.

2 Before you take Colpermin

This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

X Do not take this medicine...

- If you are allergic to peppermint oil, or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to peanuts or soya.

If any of these apply to you, **get advice from your doctor or pharmacist without using Colpermin.**

⚠ Warnings and precautions...

- Talk to your doctor or pharmacist before taking Colpermin:
- If this is the first time you have suffered from these symptoms.
 - If your symptoms worsen or do not improve within 2 weeks.
 - If you already suffer from heartburn as you may experience a worsening of this condition when taking Colpermin. If heartburn symptoms worsen you should stop taking Colpermin.
 - If you are aged 40 years or over and it has been some time since your last attack of IBS, or your symptoms have changed.
 - If you have passed blood from your bowel.
 - If you are vomiting or feeling nauseous.
 - If you have lost your appetite or have unexplained weight loss.
 - If you are unusually pale or tired.
 - If you have severe constipation.
 - If you have fever.
 - If you have recently travelled abroad.
 - If you have abnormal vaginal bleeding or discharge.
 - If you have difficulty or pain when passing urine.

⚠ Taking other medicines...

- Talk to your doctor or pharmacist...
- If you are taking any indigestion remedies.

⚠ If you are pregnant or breast-feeding

- If you are pregnant, planning a pregnancy, suspect you are pregnant or breast-feeding do not take this medicine before asking your doctor or pharmacist for advice.

⚠ Some of the ingredients can cause problems

- This product contains arachis oil (peanut oil). Do not use this medicine if you are allergic to peanut or soya.
- Peppermint oil can cause allergic reactions.

⚠ Taking with food, drink and alcohol

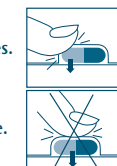
- Avoid alcoholic drink.

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3 How to take Colpermin

Check the table to see how much medicine to use.

- For oral use. Swallow capsules with a small quantity of water.
- Do not take the capsules immediately after food.
- Do not eat 30-60 minutes after taking the capsule.
- Do not take the capsules at the same time as indigestion remedies as they may damage the capsules.
- Do not chew or break the capsules before swallowing.
- Colpermin capsules are hard gelatine capsules. There is a chance that the capsules could break when they are pushed out. Push out the capsules from the blister pocket with slight pressure toward the end of the capsule. See diagram.



i Children under 15 years

Colpermin is not recommended for children under 15 years old.

i Adults and Adolescents 15 years and over

Age	Dose
Adults and children 15 years and over	Take one capsule three times a day.

If symptoms are severe, the dose can be increased to **two capsules** taken three times a day.

- Do not take capsules immediately after food.
- The capsules should be taken until symptoms are resolved, normally within one to two weeks.
- If you experience new symptoms or worsening of existing symptoms, consult your doctor.

⚠ If anyone has taken too much

If anyone has taken too many capsules, contact a doctor or your nearest Accident and Emergency department taking this leaflet and pack with you.

⚠ If you forget to take the medicine

If you forget to take a dose, take the next dose when needed. **Do not** take a double dose.

4 Possible side-effects

Colpermin can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

If you experience the following, stop using the medicine and seek immediate medical help:

- An allergic reaction including rash, headache, slow pulse rate, loss of co-ordination and shaking can occur. These may occur if the capsules are taken with alcohol.

If you experience the following, stop using the medicine and contact your doctor or pharmacist.

- Burning sensation in mouth and throat.
- Dyspepsia (indigestion).
- Heartburn.
- Nausea or vomiting.
- Anal discomfort.

Reporting of side-effects:

If you get any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side-effects not listed in this leaflet. You can also report side-effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side-effects you can help provide more information on the safety of the medicine.

5 How to store Colpermin

Do not store above 25°C. Store in original container in order to protect from light.

Keep out of the sight and reach of children.

Do not use Colpermin after the expiry date which is stated on the carton. The expiry refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What's in the medicine?

The active ingredient is: Peppermint oil 0.2 ml (187 mg). Other ingredients are: Gelatin, colloidal silica, titanium dioxide (E171), indigotine (E132), Eudragit L 30 D-55 (methacrylic acid-ethylacrylate copolymer 1:1), Eudragit S-100 (methacrylic acid-methylmethacrylate copolymer 1:2), triethyl citrate, glycerol monostearate 40-55, macrogol 4000, talc, purified water, white beeswax, refined arachis (peanut) oil.

What the medicine looks like

Colpermin capsules are coloured capsules with opaque blue cap, opaque light blue body and a dark blue band around the middle. They are available in blister packs of 20 and 100 capsules. Not all pack sizes may be marketed.

Product Authorisation Holder: Johnson & Johnson (Ireland) Limited, Airtown Road, Tallaght, Dublin 24, Ireland.
Manufacturer: Janssen-Cilag, 27100, Val de Reuil, France
QR McNeil Products Limited, Maidenhead, SL6 3UG, UK.

This leaflet was revised in April 2021
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