

**Patient Package Insert
according to Pharmacists'
Regulations
(Preparations) - 1986**

The medicine is dispensed without a doctor's prescription

Colotal tablets 135 mg

Active ingredient and its quantity:

Each tablet contains 135 mg of Mebeverine Hydrochloride. Inactive ingredients and allergens in the medicine - see in section 2 "Important information about some of the ingredients of this medicine" and in section 6 of this leaflet.

Read this entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist. This medicine can be sold without a doctor's prescription. However, the medicine should be taken carefully to get the best results from it. Keep this leaflet, you may want to read it again.

Take the medicine according to the dosage instructions in section 3 of this leaflet. Consult a pharmacist if you need additional information. Refer to the doctor if the symptoms worsen or do not improve after two weeks.

1. What is the medicine intended for?

The medicine is intended to treat spastic bowel syndrome (irritable bowel syndrome).

Therapeutic group:

Anticholinergics. Irritable bowel syndrome is a common condition that causes bowel spasms and pain. The bowel is a long muscular tube that allows the food to pass through it during digestion. If the bowel contracts too strongly, you will feel pain. This medicine acts to relax the contractions (spasms) and pain. The main symptoms of irritable bowel syndrome include:

- Stomach ache and spasms
- Feeling bloated and having gas
- Diarrhea (with or without constipation)
- Hard and small pellet-like or ribbon-like stools

These symptoms may vary from person to person. Tell your doctor if you develop new symptoms or

if the symptoms continue more than two weeks.

Your diet and lifestyle can also help treat irritable bowel syndrome: The way you restrict your diet depends on the way the syndrome affects you. If you feel that certain foods cause the symptoms, then it makes sense not to eat them. A high fiber diet may help, but ask a pharmacist for more information. Some patients find that relaxing helps to lessen their symptoms. You may find it helpful to set aside some time each day to relax.

2. Before using the medicine

Do not use Colotal if:

- You are hypersensitive (allergic) to the active ingredient mebeverine or to any of the other ingredients this medicine contains (see section 6 "Additional information" in this leaflet).

Special warnings regarding the use of this medicine

Before treatment with Colotal, refer to the doctor if:

- you have not suffered from irritable bowel syndrome in the past.
- new symptoms have appeared or there is a worsening of the existing symptoms.
- you suffer from liver or kidney problems.

Before treatment with Colotal, tell the doctor or pharmacist if:

- you are 40 years of age or older and your symptoms have changed or it has been some time since you last suffered from irritable bowel syndrome.
- there is blood in your stools.
- you have nausea or vomiting.
- you look pale and feel tired.
- you have constipation.
- you have a fever.
- you have recently travelled abroad.
- you are pregnant, planning on becoming pregnant, or breastfeeding (see below in "Pregnancy and breastfeeding").
- you are a woman and have unusual bleeding or discharge from your vagina.
- you experience difficulty or pain when urinating.

The doctor will tell you if the medicine is safe for you to use.

Children and adolescents

There is no information about the safety and efficacy of using this medicine in children and adolescents. The use of

this medicine in children and adolescents under the age of 18 is not recommended.

Drug interactions

If you are taking, or have recently taken other medicines, including non-prescription drugs and nutrition supplements, tell the doctor or pharmacist.

There are no known drug interactions with the medicine.

Use of this medicine and food It is recommended to take the tablet 20 minutes before a meal.

Use of this medicine and alcohol consumption

As far as is known, drinking alcohol has no influence on the medicine Colotal.

Pregnancy and breastfeeding

Pregnancy: Consult the doctor or pharmacist before taking Colotal if you are pregnant or planning to become pregnant. There is limited information about the safety of using Colotal in pregnant women. Your doctor may recommend that you stop treatment with Colotal before becoming pregnant or once you know that you are pregnant. **Breastfeeding:** Do not use Colotal if you are breastfeeding. If you are breastfeeding, consult the doctor before using the medicine.

Driving and use of machinery

This medicine should not affect your ability to drive, use tools or machinery.

Important information about some of the ingredients of this medicine

This medicine contains lactose and sucrose (sugars). If you are sensitive to certain sugars, consult a doctor before starting treatment.

3. How should you use this medicine?

Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine. The usual recommended dosage is: One tablet, three times a day.

Do not exceed the recommended dose.

Method of administration

It is recommended to take the tablet approximately 20 minutes before a meal; Try to take the tablets at set times every day and at equal intervals, so that taking the tablets will be spread

out throughout the whole day. Swallow the tablet whole with water. The tablet is coated. Do not chew the tablet because of an unpleasant taste. There is no information on crushing or halving.

If you have accidentally taken a higher dosage

If you have taken an overdose or if a child or someone else has accidentally swallowed the medicine, proceed immediately to the doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to take Colotal

If you forgot to take Colotal at the set time, do not take a double dose. Take the next dose at the usual time and consult the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of Colotal, consult the doctor or pharmacist.

4. Side Effects

As with any medicine, the use of Colotal can cause side effects in some users. Do not be alarmed while reading the list of side effects. You might not suffer from any of them.

Stop the taking the medicine and refer to a doctor immediately if the following signs appear:

Difficulty breathing, swelling of the face, neck, tongue or throat (severe allergic reactions).

Additional side effects:

You may suffer from a mild allergic reaction to the medicine, such as: skin rash, redness and itching of the skin.

If a side effect appears, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health via the link "Reporting Side Effects from Drug Treatment" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link: <https://sideeffects.health.gov.il>

Additionally, you can report to Perrigo via the following address: www.perrigo-pharma.co.il

5. How to store the medicine

- Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package and blister package. The expiry date refers to the last day of that month.
- Store in a cool place, below 25°C.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer needed. These measures will help protect the environment.

6. Additional Information

- In addition to the active ingredient, the medicine also contains: Lactose monohydrate, Sucrose, Talc, Potato starch, Povidone 25, Magnesium stearate, Gelatin, Acacia spray dried, Carmauba wax.
- What the medicine looks like and contents of the package:
The tablets are packaged in blister trays. Each blister contains 10 tablets.
There are a number of marketed packages that contain 20, 50, or 100 tablets. Not all package sizes may be marketed.
- The manufacturer, registration holder, and address: Perrigo Israel Pharmaceuticals, Ltd., P.O.B. 16, Yeruham.
- Revised in April 2020.
- Drug registration number at the national medicines registry of the Ministry of Health: 3572.25831

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