

**PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

The medicine is dispensed without a doctor's prescription

Colotal Tablets 135 mg

Each tablet contains 135 mg Mebeverine hydrochloride.

Inactive and allergenic ingredients in the preparation – see section 6 “Further Information” and section 2 “Important information about some of the ingredients of the medicine” in this leaflet.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. Take the medicine according to the instructions in the dosage section of this leaflet. Consult with the pharmacist if you require further information. Refer to the doctor if symptoms of the illness worsen or do not improve.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended to treat Irritable bowel syndrome and conditions included in this group such as: Chronic irritable colon, Gastro-intestinal spasm secondary to organic diseases.

Therapeutic group: Anticholinergics.

The bowel is a long, muscular tube that allows food to pass through it during the digestion process. If the bowel contracts too strongly, you will feel pain. This medicine acts to relax the contractions (spasms) and the pain.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

you are **sensitive** (allergic) to the active ingredient mebeverine hydrochloride or to any of the additional ingredients contained in the medicine (see section 6 “Further Information” in this leaflet).

Children and adolescents:

This medicine is not generally intended for infants, children and adolescents under 18 years of age.

Drug interactions:

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

Pregnancy and breastfeeding:

- If you are pregnant or plan to become pregnant, consult the doctor. Colotal is not recommended during pregnancy. The doctor may advise you to stop treatment with Colotal or to take a different medicine.
- If you are breastfeeding or start to breastfeed, consult the doctor. Colotal is not recommended when breastfeeding. The doctor may advise discontinuing breastfeeding or recommend taking a different medicine if you are interested in breastfeeding.

Driving and using machinery:

As far as is known, Colotal does not have an effect on driving or the use of machines.

Important information about some of the ingredients of the medicine:

The medicine contains lactose and sucrose. In case of an intolerance to certain sugars, consult the doctor before starting treatment.

3. HOW SHOULD YOU USE THE MEDICINE?

- Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
- The usual dosage is one tablet 3 times a day.
- **Do not exceed the recommended dosage.**

Method of administration:

- Take one tablet with a full glass of water.
- It is recommended to take the tablet approximately 20 minutes before the meal.
- Try to take the tablets at set times each day and at equal intervals so that administration of the tablets will be spread across the day.
- Do not chew, crush or halve the tablet.

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

If you forget to take this medicine at the designated time do not take a double dose. Take the next dose at the scheduled time.

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 the use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

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

Stop taking the medicine and refer to a doctor immediately if the following signs occur; you may need medical treatment:

- Difficulty breathing, swelling of the face, neck, lips, tongue or throat. You may be suffering from a severe allergic reaction to the medicine.

Additional side effects:

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

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

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link “Reporting Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

In addition, you can report to Padagis by entering the link: www.padagis.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order 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 carton and blister package. The expiry date refers to the last day of that month.
- Store in a cool place, below 25°C.

6. FURTHER INFORMATION

- In addition to the active ingredient the medicine also contains: Lactose Monohydrate, Sucrose, Potato Starch, Talc, Povidone 25, Magnesium Stearate, Gelatin, Acacia, Carnauba Wax. Each tablet contains 97 mg lactose and 79 mg sucrose.

- What the medicine looks like and the contents of the package: The tablets are packaged in blisters. Each blister contains 10 white tablets. There are package sizes that contain 20, 50 or 100 tablets. Not all package sizes may be marketed.

- Manufacturer and registration holder and its address: Padagis Israel Pharmaceuticals, Ltd., 1 Rakefet St., Shoham.

- Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Colotal Tablets 035-72-25831-00.

Revised in September 2023 according to MOH guidelines.