

Guidance-mandatory medicines

Medication for the Relief of Irritable Bowel Syndrome (IBS) **ギュラック****Precautions for use****What you should Not do:**

(If you do not follow the precautions listed below, your current symptoms may worsen and you may be at an increased risk of side effects.)

1. The following persons should not take this medicine.
 - (1) Persons who have never been diagnosed with or treated for IBS by a physician
 - (2) Persons who are unsure whether their symptoms are a recurrence of IBS (for example, the current symptoms are different from those experienced when they were previously diagnosed with or treated for IBS)
 - (3) Persons with the following symptoms:
 - Needing to use the toilet to have a bowel movement or experiencing abdominal pain at night, including during sleep.
 - Having a fever.
 - Having joint pain.
 - Having mucous and bloody stools.
 - Having repeated severe diarrhea.
 - Having acute severe diarrhea.
 - Having abdominal pain that does not improve after a bowel movement.
 - Experiencing vomiting.
 - Having unexpected weight loss of 3 kg or more within the past 6 months.
 - (4) Persons who have experienced any of the following diseases:
Colorectal cancer, inflammatory bowel disease (Crohn's disease, ulcerative colitis)
 - (5) Persons who have undergone open abdominal surgery and have the following symptoms (as these symptoms may cause gastrointestinal obstruction):
Severe constipation with abdominal distension (symptoms suggestive of gastrointestinal obstruction)
 - (6) Persons receiving the following treatments:
Acute abdominal diseases (appendicitis, intestinal hemorrhage, ulcerative colitis, etc.), hypercalcemia, renal calculi, renal failure (excluding dialysis)
 - (7) Persons who have had allergies to this medicine or ingredients of this medicine
 - (8) Persons who have difficulty swallowing (persons who feel that they have difficulty swallowing food, etc.)
 - (9) Children aged under 15 years and the elderly aged 75 years or older
2. Do not take any of the following medicines while taking this medicine.
Medicines containing medications for the relief of IBS symptoms (e.g., trimebutine maleate), active vitamin D preparations (e.g., alfacalcidol), calcium preparations (e.g., calcium lactate), cardiac glycosides (e.g., digoxin), antibiotics (e.g., tetracycline and norfloxacin), proton-pump inhibitors (e.g., omeprazole), H2 blockers (e.g., famotidine and ranitidine), and antacids (e.g., aluminum hydroxide gel and magnesium hydroxide)
3. Do not take this medicine regularly for long periods.

Who should seek consultation

1. The following persons should consult a doctor or pharmacist before taking this medicine:
 - (1) Persons under treatment by a doctor
 - (2) Persons who are or may be pregnant
 - (3) Persons aged 50 years or older
 - (4) Persons with anemia
 - (5) Persons who have experienced allergic symptoms to medicines
 - (6) Persons diagnosed as having the following:
Diabetes mellitus, thyroid disease, hyperparathyroidism
 - (7) Persons likely to develop hypercalcemia (e.g., vitamin D toxicity)
 - (8) Persons who have or are suspected of having absent or decreased gastric acid secretion
 - (9) Persons who have a family member with colorectal cancer or inflammatory bowel disease
 - (10) Persons with severe abdominal pain or constipation
 - (11) Persons undergoing dialysis
2. Stop taking this medicine immediately and ask a doctor or pharmacist with this leaflet if the following symptoms appear after taking this medicine because they may be side effects of the medicine.

Affected area	Symptoms
Skin	Rash, itching
Digestive organs	Nausea/vomiting, dry mouth, abdominal distension, diarrhea, constipation, abdominal pain, stomach rumbling
Liver	General malaise, yellowing of the skin and white part of the eye
Other	Edema, blood in the urine, urine protein, headache, acute high fever, chills, sore throat

3. If symptoms do not improve after taking this medicine for about 2 weeks, stop taking this medicine and ask a doctor or pharmacist with this leaflet.

INDICATIONS

Relief of the following symptoms of IBS: Repeated or alternating diarrhea and constipation associated with abdominal pain or abdominal discomfort (for use only by persons who have previously been diagnosed with and treated for IBS by a physician)

DOSAGE AND DIRECTIONS

Take the following amount of medicine after meal with water.

Age	One dose	Daily number of taking
Adult (15 years or over)	1 tablet	3 times
Under 15 years and 75 years or over	× Do not take	

<Precautions regarding dosage and directions>

- (1) Please follow the designated dosage and directions.
- (2) Take the tablet with a glass (about 180 mL) of water. (If taken without water, the tablet may become lodged in the throat or esophagus.)
- (3) Do not split or crush the tablet, or take it with medication-administration aids, such as swallowing jelly or thickening agents. (The tablet may swell and become lodged in the throat or esophagus.)
- (4) Do not take the tablet at the same time as dietary supplements in tablet or capsule form. (The tablet or supplements may become lodged in the throat or esophagus.)
- (5) Even if symptoms improve, this medicine should not be taken for more than 4 weeks.

INGREDIENTS AND CONTENTS

In one daily dose (3 tablets)

Ingredients	Contents	Actions
Polycarbophil calcium	1500mg (as the dried substance)	This medicine absorbs water in the intestine to help normalize stool consistency.

As inactive ingredients, this medicine contains cellulose, CMC, hydroxypropyl cellulose, magnesium stearate, hypromellose, macrogol, titanium oxide, polyvinyl acetal diethylamino acetate, carnauba wax.

PRECAUTIONS FOR STORAGE AND HANDLING

- (1) Store this medicine in a dry and cool place away from direct sunlight.
- (2) Keep out of the reach of children.
- (3) Do not transfer this medicine to another container (it may cause improper use or loss of quality).
- (4) Do not handle this medicine with wet hands.

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