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This product is manufactured and marketed for domestic sales in accordance with the Japanese laws. This leaflet, translated from the original package insert created in accordance with Japanese laws, is not in compliance with laws outside Japan.

Designated 2nd Class OTC drug

Please read the package insert carefully before use and keep it with this medicine.

Antidiarrheal medicine



# Precautions for use

#### To be avoided

(Failure to follow the directions below may worsen existing symptoms or increase the risk of adverse reactions/accidents)

1. Do not use if you:

Have had an allergic reaction to this medicine or any of its ingredients.

**2.** Do not use the following medicines while taking this medicine. Gastrointestinal analysesics and antispasmodics

3. Do not drive or operate machinery after use.

(Sleepiness, etc. may occur.)

4. Do not drink alcohol before and after use.

### What to ask a doctor, pharmacist or registered salesperson

- 1. Ask a doctor, pharmacist or registered salesperson before use if you:
  - (1) Are currently treated by a doctor.
  - (2) Have diarrhea with fever, bloody stool, or continuous mucous stool.
  - (3) Have acute severe diarrhea or diarrhea with any of symptoms such as abdominal pain/abdominal bloating/nausea, etc.
    - (If diarrhea is stopped forcefully with this medicine, the disease may worsen.)
  - (4) Have an anal disease, etc. which constipation should be avoided.
    - (After taking this medicine, constipation may occur.)
  - (5) Are pregnant or may possibly be pregnant.
  - (6) Are breastfeeding.
  - (7) Are elderly.
  - (8) Have ever had allergic reaction to any medicines, etc.
- 2. The following symptoms, occurred due to this medicine, may be observed as adverse reactions. If any of the symptoms occur after use, stop use immediately and ask a doctor, pharmacist or registered salesperson with the package insert.

| Related area          | Symptom  |
|-----------------------|--|
| Skin                  | Rash/redness, itching  |
| Digestive organs      | Loss of appetite, abdominal pain, nausea, feeling of fullness in the abdomen, constipation, abdominal distress, vomiting |
| Psychoneurotic system | Dizziness  |

The following serious symptoms may rarely occur. In such cases, ask a doctor and receive medical treatment immediately.

| Name of symptom   | Symptom   |
|---|---|
| Shock (anaphylaxis)   | Symptoms such as itchy skin, hives, hoarseness, sneezing, itchy throat, difficulty in breathing, palpitation and clouding of consciousness may occur immediately after use. |
| Oculo-muco-cutaneous<br>syndrome (Stevens-Johnson<br>syndrome), toxic epidermal<br>necrolysis | Symptoms such as high fever, ocular hyperemia, eye discharge, lip erosion, sore throat, widespread rash/redness of the skin, etc. may persist or worsen suddenly.           |
| Ileus-like symptoms (intestinal obstruction-like symptoms)                                    | Severe abdominal pain, stop of discharge of intestinal gas (flatus), vomiting, or severe constipation with feeling of fullness in the abdomen may occur.                    |

- 3. The following symptoms may occur after use; in case these symptoms persist or worsen, stop use and ask a doctor, pharmacist or registered salesperson with the package insert.

  Sleepiness
- 4. If symptoms do not improve after using for 2 to 3 days, stop use and ask a doctor, pharmacist or registered salesperson with the package insert.

#### **Indications**

Diarrhea, diarrhea due to excessive eating/drinking, diarrhea triggered by cold air while sleeping, diarrhea associated with abdominal pain, food poisoning, water poisoning, loose stools

# Dosage/directions

Take the tablets with room temperature or warm water. However, do not take after diarrhea stops. Also, take at intervals of more than 4 hours.

| Age                              | One dose             | Daily dose |
|----------------------------------|----------------------|------------|
| Adults (15 years and older)      | 3 tablets 🔾 🔾 🔾      | Twice      |
| Children (Under 15 years of age) | <b>★</b> Do not use. |            |

# <Pre><Pre>cautions for dosage/directions>

- (1) Follow the dosage/directions.
- (2) How to take out tablets:

As shown on the right, strongly press the convex part of the PTP sheet with your finger tip to break the aluminum foil on the back and take out a tablet. (Accidental swallowing the PTP sheet may cause an unexpected accident, such as esophageal mucosa penetration, etc.)



# Ingredients/contents (in 6 tablets)

| Ingredients/contents       | }       |
|----------------------------|---------|
| Loperamide hydrochloride   | 1.0mg   |
| Berberine chloride hydrate | 80.0mg  |
| Acrinol hydrate            | 80.0mg  |
| Powdered peony root        | 200.0mg |
| Powdered geranium herb     | 300.0mg |

[Inactive ingredients] Lactose, cellulose, croscarmellose sodium, hydroxypropyl cellulose, calcium silicate, magnesium stearate, hypromellose, triacetin, talc, titanium oxide, Yellow No.5, carnauba wax

#### Precautions for storage and handling

- (1) Store in a cool and dry place avoiding high temperatures, humidity, and direct sunlight.
- (2) Keep out of reach of children.
- (3) Do not transfer the product to another container. (It may cause misuse and deterioration in the quality.)
- (4) Store and handle this product carefully so as not to break the aluminum foil of the PTP sheet or to damage the tablets inside.
- (5) Do not use this product after its validity date has expired (printed on the outer box).

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Y1280R H6K