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This product is manufactured and marketed for domestic sales in accordance with the Japanese laws.  
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Designated 2nd Class OTC drug

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

Antidiarrheal medicine

## トメダイニュー錠 Tomedain Kowa Tablet

### 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 analgesics and antispasmodics

**3. Do not drive or operate machinery after use.**

(Sleepiness 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 stools, or continuous mucous stools.

(3) Have acute severe diarrhea or diarrhea with any of symptom 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 package insert.**

Related area	Symptom
Skin	Rash/redness, itching
Digestive organs	Loss of appetite, abdominal pain, nausea, feeling of fullness in the stomach and abdomen, constipation, abdominal distress, vomiting
Central nervous system	Dizziness

The following serious symptoms may rarely occur. In such a case, 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 syndrome (Stevens Johnson syndrome), toxic epidermal 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 abdominal fullness may occur.

(Continued overleaf)

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 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 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 and directions

Take the tablets with room temperature or warm water. However, do not take after diarrhea stops.

Take at intervals of 4 hours or more.

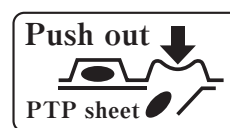
Age	One dose	Daily dose
Adults (15 years and older)	3 tablet ○○○	Twice
Children (Under 15 years of age)	Do not use.	

#### <Precautions for dosage and directions>

(1) Follow the dosage and 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 push out a tablet. (Accidental swallowing the PTP sheet may cause 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 (printed on the outer box) has expired.

Marketing Authorization Holder: Kowa Company, Ltd. 3-4-14, Nihonbashi-Honcho, Chuuo-ku, Tokyo

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