

Product information

【Drug Facts】



<Kyowa-Gifu-Japan>

Please be sure to read this product information carefully before use. Keep this product information in a safe place so that you can read again, when you need it.

Class 3 drugs **Antidiarrheal medicine** (TABLETS)

Can be taken without water

Diarrhea・food poisoning・water poisoning

MAIKUROMIN GERIDOME EX

Characteristic

○Berberine tannate is decomposed into berberine and tannic acid in the intestines, and its bactericidal and astringent effects are effective against bacterial diarrhea and diarrhea caused by abnormal fermentation in the intestines.

○Roto extract is effective against diarrhea accompanied by abdominal pain due to gastrointestinal spasms.

○This medicine is a chewable tablet that dissolves in the mouth and can be taken without water.

Active ingredients

<in 6tablets/daily dose>

Effects

Berberine tannate 300mg	Antidiarrheal drug (antidiarrhea) with intestinal sterilization effect
3 triturated powder of Roto extract 180mg... (equivalent to 60mg as Roto extract)	Antidiarrheal drug that suppresses increased intestinal motility

<PRECAUTIONS CONCERNING INGREDIENTS>

Since this medicine is a formulation using crude drug raw materials, the color tone of the tablet may vary slightly depending on the product, but the effectiveness remains the same.

Indication

Diarrhea, diarrhea due to indigestion, food poisoning, vomiting and purging, water poisoning, loose bowels, soft stool, and diarrhea accompanied by abdominal pain



【 Precautions 】

When not to use the product

(Failure to observe the following may result in the current symptoms worsening or adverse reactions occurring.)

1. While taking this medicine, please do not take any of the following medicines.

People with phenylketonuria. (This medicine contains L-phenylalanine compound.)

2. While taking this medicine, you should not used in combination with the following medicines:

Pain relief/antispasmodic medicine for the stomach, other gastrointestinal medicine containing scopolia extract, medicine for motion sickness

3. After taking this drug, do not drive a car or operate machinery.

(symptoms such as blurred vision and abnormal brightness may occur)

4. Nursing women should either not take this medicine or stop nursing while taking this medicine.

(the medicine may be transferred to the breast milk and accelerate the pulse of the infant.)



Consult a doctor for the following

1. The following persons should consult a doctor, pharmacist, or registered distributor before using this medicine.

- (1) Patients undergoing medical treatment from a doctor.
- (2) Those who have diarrhea with fever, bloody stool or persistent mucous stool.
- (3) Those who have acute and severe diarrhea or diarrhea with accompanying symptoms such as abdominal pain/abdominal distension/sick feeling.

(The disease may worsen by taking this medicine to stop diarrhea.)

- (4) Pregnant women or women suspected of being pregnant.
- (5) The elderly
- (6) Patients who have experienced allergic symptoms associated with drugs, etc.
- (7) Persons with the following symptoms :
urination difficulty
- (8) Persons diagnosed as having the following :
heart disease、Glaucoma

2. The following symptoms may be adverse reactions to this medicine. If any of these symptoms occur, discontinue use immediately and consult a doctor, pharmacist, or registered salesperson with this Japanese Product information.

Related area	Symptoms
Digestive organ	Rash ・ redness, itching
Cental nervous system	Headache
Circulatory organ	Difficulty urinating
Others	Facial hot flashes、abnormal brightness

3. The following symptoms may appear after taking it, so if such symptoms persist or increase. Please stop taking it and consult a doctor, pharmacist or registered salesperson with the Japanese package insert.

Dry mouth、blurred vision

4. If symptoms do not improve even after using this medicine for 5 to 6 days, stop taking this medicine and consult a physician, pharmacist or registered salesperson, being sure to take the Japanese package insert with you.

Other precautions

Some may have trouble lactating.

Directions

Please take the following amount.

Age	One dose	Number of doses per day
Adult (15 years old and over)	2 tablets	Take the medicine at a time up to three times a day by chewing or dissolving it in the mouth, in intervals of at least 4 hours
Over 12 years old and under 15 years old	1 tablet	
under 12 years old	Do not use	

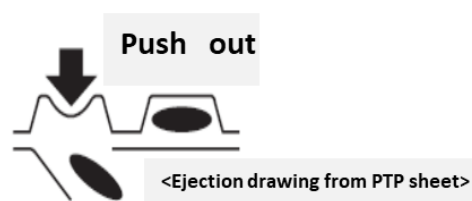
〈When using this product〉

- (1) Please follow the recommended dosage and directions.

When allowing children (8 years old and over) to use the medicine, a guardian must be present to watch and tell such them how to use it.

- (3) How to take out tablets.

As shown in the image on the right, firmly press the convex part of the PTP sheet containing the tablet with your fingertips, break the aluminum foil on the back, take it out, and take it.



(If you accidentally swallow it whole, it may lead to unexpected accidents such as sticking to the esophageal mucosa.)

Precautions for storage and handling

- (1) Store in a cool and dry with less humidity place free from direct sunlight.
- (2) Keep all medicine out of the reach of children.
- (3) Do not transfer this medicine to a different container. (In this case, cause misuse or change quality.)
- (5) Please do not take the product past the expiration date on the label. not take products that have passed the expiration date.

Inactive ingredients:

Contains potato starch, D-mannitol, Mg aluminate metasilicate, tannic acid, povidone, crospovidone, aspartame (L-phenylalanine compound), citric acid hydrate, L-menthol, fragrance, and Mg stearate.

Contact information for the Relief System for Side Effects

Pharmaceuticals and Medical Devices Agency

http://WWW.pmda.go.jp/kenkouhigai_cmp/index.html

Telephone: 0120-149-931 (toll-free)

Questions or comments?

If you have any questions about this medicine, please contact the store where you purchased it or the number below.

Manufacturer: Teika Pharmaceutical Co., Ltd. Customer Service Department

☎ 076-431-8863

Reception hours 9:00-17:00 (excluding Saturdays, Sundays, and holidays)

Trader: Consumer Consultation Desk: Kyowa Pharmaceutical Industry Co., Ltd.

Customer consultation room ☎ 058-246-8771



Reception time 9:00~12:00・13:00~17:00 (Excluding weekends and holidays)

[Request of limited correspondence] <Kyowa-Gifu-Japan>

- (1) In case of telephone consultation, please only in Japanese for a while.
- (2) The latest Japanese package insert is available on the website of Kyowa Pharmaceutical Co., Ltd. (www.kyowa-ci.co.jp).

Disclaimer statement

- (1) We use a format similar to the FDA OTC Drug Regulations, but this is not an OTC Drug approved under the FDA. Please note that it is licensed for domestic use in accordance with the Pharmaceutical Affairs Law of Japan.
- (2) This English translation was created by a manufacturer and distributor, but Japanese is a correct sentence and it should be as a reference material. In the case of any discrepancy between the two versions, the original Japanese version prevails.
- (3) The provider of this translation shall not be responsible for any damage that may be attributed to the use of the translation.
- (4) Do not use for commercial purpose reproduction, publication etc. of this English translation.
- (5) Although the English translation is prepared on the basis of the Japanese version of the attached document on the year and month, the attached document is revised from time to time, so the English translation may not be the latest.