

# 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 ② drugs

**Cold Remedies**

(TABLETS)

## BERSADAN ACE JYOU PLUS

● The initial symptoms of a cold include a runny and stuffy nose, followed by a cough, headache, chills, and fever. "BERSADAN ACE JYOU PLUS" is a general cold medicine that contains antipyretic analgesics, antitussive expectorants, antihistamines, etc. to quickly alleviate the symptoms of colds.

### Active ingredients (in 9 tablets/daily dose)

### Effects

Acetaminophen 300mg	Lower fever and relieve pain
Etenzamide 700mg	Makes it easier to get rid of phlegm from the throat
Clemastine fumarate 1.34mg (as clemastine)	Control cold allergy symptoms (sneezing, runny nose, stuffy nose)
Dihydrocodeine phosphate 24mg	relieve cough
dl-Methylephedrine hydrochloride 60mg	Relieve cough and suppress phlegm
Anhydrous Caffeine 75mg	relieve headache
Licorice dried extract 250mg (equivalent to 1,000mg of the herbal medicine Glycyrrhiza Radix)	suppress inflammation
Calcium ascorbate 500mg	Vitamin C supplementation
Thiamine nitrate 25mg	Vitamin B1 supplementation
Riboflavin 12mg	Vitamin B2 supplementation

### Indication

Alleviation of cold symptoms such as runny nose, stuffy nose, sneezing, sore throat, cough, sputum, chills (since due to fever), fever, headache, joint pain, muscle pain.



### Precautions

**[When not to use the product]**



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

**1. Do not take to the following person:**

- (1) Patients who have had an allergic symptom to this medicine or its ingredients.
- (2) Patients who have experienced asthma from taking this drug or other cold remedies, antipyretic analgesics.
- (3) Children under 15 years old.
- (4) Pregnant women within 12 weeks of due date.

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

Other medicines for cold, antipyretic analgesics, sedatives, antitussive expectorants, and internal medicines containing antihistamine etc. (internal medicine for rhinitis, motion sickness medicine, allergy medicine etc).

- 3. Do not drive a motor vehicle or operate machinery after taking this medicine. (Symptoms as drowsiness may occur.)**
- 4. Nursing women should either not take this medicine or stop nursing while taking this medicine.**
- 5. Do not drink alcohol before or after taking this medicine.**
- 6. Do not take this medicine for more than 5 days**

**[Consult a doctor for the following]**



- 1. The following persons should contact a physician, pharmacist, or registered salesperson for a consultation before administration.**
  - (1) Patients undergoing medical treatment from a physician or dentist.
  - (2) Pregnant women or women suspected of being pregnant.
  - (3) The elderly
  - (4) Patients who have had an allergic symptom to this medicine or its ingredients.
  - (5) Persons with the following symptoms:: High fever、 Difficulty urinating
  - (6) Persons diagnosed as having the following .Thyroid dysfunction, diabetes, heart disease, high blood pressure, liver disease, kidney disease, glaucoma, systemic lupus erythematosus, mixed connective tissue disease, respiratory dysfunction, obstructive sleep apnea syndrome, obesity.

(7) Patients who experienced any of the following diseases. Gastric • duodenal ulcer, ulcerative colitis, Crohn's disease

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 the Japanese package insert.

Related area	Symptoms
Skin	Rash • redness, itching
Digestive organ	Nausea/vomiting, loss of appetite, stomach discomfort, stomach pain, stomatitis, heartburn, heaviness in the stomach, gastrointestinal bleeding, abdominal pain, diarrhea, bloody stools
Mental nervous system	Dizzy
Cardiovascular system:	Palpitations
Respiratory system:	Shortness of breath
Urology	Urination difficulty
Others	Blurred vision, ringing in the ears, swelling, nosebleeds, bleeding gums, difficulty in stopping bleeding, bleeding, back pain, excessive drop in body temperature, feeling tired

In very rare cases the following serious symptoms may occur. In this case, please get medical attention immediately.

Symptoms' name	Symptoms
Shock(Anaphylaxis)	Immediately after taking the medicine, itchy skin, urticaria, faint voice, sneezing, itchiness, breathing difficulty, palpitation, turbidity of consciousness, etc. appear.
Oculomucocutaneous syndrome (Stevens–Johnson syndrome), toxic epidermal necrolysis, acute generalised exanthematous pustulosis:	Hyperthermia, ocular hyperaemia, eye discharge, lip erosion, pain throat, widespread skin rash/redness, small pimples (small pustules) on reddened skin, general malaise, anorexia, etc. may persist or suddenly worsen.

Liver dysfunction	It shows fever, itching, rash, jaundice (yellowing of the skin and whites of the eyes), brown urine, whole body dullness, loss of appetite, etc. appear.
Renal disorder	Fever, rash, decreased urine volume, whole body swelling, whole body sagging, joint pain (sore throat), diarrhea, etc. appear.
Aseptic meningitis	Severe headaches accompanied by stiffness in the neck, fever, nausea, and vomiting occur. (Such symptoms are particularly frequently reported in people receiving treatment for systemic lupus erythematosus or mixed connective tissue disease.)
Interstitial pneumonia	If you go up the stairs or do a little impossible, you will be out of breath, Nausea / vomiting and feel stuffy, fever etc. These are suddenly appeared or persisted.
Asthma	Symptoms, such as wheezing or hissing when breathing, and difficult breathing, etc. may occur.
Aplastic anemia	Bruising, nosebleeds, gum bleeding, fever, skin and mucous membranes appear pale, fatigue, palpitations, shortness of breath, mood worsening, bloodsheds etc. appear.
Agranulocytosis	Sudden high fever, chills, sore throat etc. appear.
Respiratory depression	Constipation, Shortness of breath, breathing difficulties and so may appear.

- 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.

Constipation, Thirst, Sleepiness

- 4.** If these symptoms are not good even after taking between 5 and 6 times, please stop taking the medicine and consult a doctor, pharmacist or registered salesperson with the Japanese package insert.

## Dosage and administration

Please take the following dosage three times a day within 30 minutes after meals.

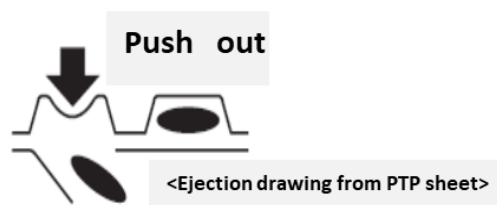
Age	One dose	Number of doses per day
Adult(15 years old and over)	3 tablets	3 times
under 15 years old	Do not use	

### 〈When using this product〉

- (1) Please follow the recommended dosage and directions.
- (2) How to take out tablets. (as to a PTP product),

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)
- (4) The padding inside the bottle is to prevent the tablets from being damaged during transportation. After opening, please remove it as it is no longer needed. (In stock in bottles)
- (5) Make sure to tightly close the lid of the bottle. If it is not tightened properly, it may deteriorate due to moisture etc. (In stock in bottles)
- (6) Do not handle this drug with wet hands. (If water gets on the tablet, part of the surface may melt, causing discoloration or uneven color.)
- (7) Please do not take products that have passed the expiration date

## Inactive ingredients:

Lactose, polyvinyl alcohol/acrylic acid/mer methacrylate copolymer, Mg stearate, macrogol, talc, polyvinyl alcohol (partially saponified), cross-CMC-Na, hypromellose, titanium oxide, iron sesquioxide

## *Questions or comments?*

If you have any suggestions about this product, please contact the shop you purchased or the following address.

Consumer consultation window: 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](http://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) This English translation has been created based on the Japanese attached document, but since the attached document is revised from time to time, it may not be the latest translation.