

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 medicine

(GRANULES)

SOUGOUKANBOUYAKU ACE BIRYU

This general cold medicine contains vitamin B1 and B2 to prevent exhaustion, as well as 8 active ingredients that suppress pain symptoms in the cold, headache, cough, nose, throat, and so on.

Active ingredients (in 3 packets/daily dose) Purpose

(1.200mg in 1 Packet)

Acetaminophen 900mg	Antipyretic analgesic
dl-Methylephedrine hydrochloride 60mg	Bronchodilator
Tipepidine hibenzate 50mg	Anti-cough
Chlorpheniramine maleate 7.5mg	Anti-allergy
Guaifenesin 200mg	Antitussive expectorant
Anhydrous Caffeine 75mg	Headache treatment
Thiamine nitrate 20mg	Vitamin B1 supplementation
Riboflavin 4mg	Vitamin B2 supplementation

- Don't worry about taking this medicine, if urine may become yellow, so this is due to riboflavin in this medicine.

Uses

Relaxation of various symptoms of colds (runny nose, stuffy nose, sneeze, sore throat, cough, sputum, chills, fever, headache, joint pain, muscle pain)

Warnings

Do not take infants under one years old.

[To be avoided]

(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) A person with a medical history of being allergic to this medicine or substance in it.
- (2) A person who have ever had asthma taking this medicine or other cold medicine, antipyretic analgesics.
- (3) A person on dialysis.

2. While taking this medicine, you should not use 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 using this medicine. (Symptoms as drowsiness may occur.)

4. Do not drink alcohol before or after taking this medicine.

5. Do not use in long-term continuously.

[Consultation]

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

- (1) A person undergoing medical treatment from a doctor or dentist..
- (2) A pregnant woman or a woman suspected of being pregnant.
- (3) A breastfeeding woman.
- (4) Senior persons.
- (5) A person with a medical history of being allergic to medicines and other substances.
- (6) A person with symptoms of high fever and difficulty urinating.
- (7) A person who have been diagnosed with thyroid dysfunction, diabetes, heart disease, hypertension, liver disease, kidney disease, gastric/duodenal ulcer, 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 distributor with the Japanese package insert.

Related area	Symptoms
Skin	Rash · Redness, itching
Digestive organ	Nausea / vomiting, loss of appetite
Mental nervous system	Dizzy
Urology	Dysuria
Others	Excessive hypothermia

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

Symptoms' name	Symptoms
Shock(Anaphylaxis)	Symptoms, such as itching of skin, urticaria, hoarseness, sneezing, itchy throat, breathing difficulties, palpitations, and clouding of consciousness may occur immediately after take.
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.
Hepatic function failure	Symptoms, such as fever, itching, rash, jaundice (yellowing of skin and white of eyes), brown urine, general malaise, loss of appetite, etc. may occur.
Kidney disorders	Fever, rash, <u>decreased urine volume</u> * ,whole body swelling, whole body sagging, joint pain (node pain), diarrhea, etc. appear.
Aseptic meningitis	Symptoms, such as severe headache with a tight sensation along the neck, fever and feeling nausea/vomiting, etc. may occur. (these symptoms are frequently reported particularly in patients under treatment for systemic lupus erythematosus or mixed connective tissue disease.)

Interstitial pneumonia	Shortness and/or difficulties of breath when go upstairs or overwork, sudden dry cough and/or fever and its continuance
Asthma	Symptoms, such as wheezing or hissing when breathing, and difficult breathing, etc. may occur.
Aplastic anemia	Symptoms, such as bruises, nose bleeds, bleeding gums, fever, pale appearance of skin and mucosa, fatigue, palpitations, shortness of breath, becoming dizzy from feeling sick and blood in the urine, etc. may occur.
Agranulocytosis	Symptoms, such as acute high fever, chills and sore throat, etc. may occur.

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 distributor with the Japanese package insert.

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 distributor with the Japanese package insert.

Directions

Please take 1 time as possible within 30 minutes after meals, on three times a day.

Age	One dose	Number of doses per day
adult and children 15 years over	1 packet	3 times after meal
11 years old and under 15 years old	2/3 packet	
7 years old and under 11 years old	1/2 packet	
3 years old and under 7 years old	1/3 packet	
1 year old and under 3 years old	1/4 packet	
Infant under one year	Do not use	

[When using this product]

- Please follow the recommended dosage and directions.

- This medicine should be given to children only under adult supervision.
- Infant under one year old should be given priority to see a doctor and should be taken only when it is unavoidable.

Other information

- (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) If you take medicine after dividing one packet, please fold the mouth of the packet and store it, please take it within 2 days.
- (5) Please do not take products that have passed the expiration date

Inactive ingredients:

Carbonic acid carbonate, Cellulose, Lactose, Potato starch, Hydroxypropyl cellulose, Metaaluminate aluminate Mg, Glycyrrhizic acid 2K

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).

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