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

(GRANULES)

SURUURON EX KARYU PLUS

The initial symptoms of the cold start with a runny nose, stuffy nose, followed by cough, headache, chills, fever etc.

"SURUURON EX KARYU PLUS" is comprehensive cold medicines containing antipyretic analgesics, antitussive expectorants, antihistamines, etc. so as to alleviate symptoms of such colds as soon as possible.

Active ingredients (in 3 packages/daily dose) Effects

Acetaminophen 300mg····· Antipyretic analgesic Etenzamide 700mg······ Antipyretic analgesic Anhydrous Caffeine 75mg····· Headache treatment 24mg Dihydrocodeine phosphate Anti-cough dl-Methylephedrine hydrochloride 60mg Bronchodilator Expectorant effect (promotes airway Potassium guaiacol sulfonate 250mg····· secretion and reduces phlegm Reduce sneezing, runny nose and Chlorpheniramine maleate 7.5mg······ stuffy nose Gastrointestinal weakness, fatigue, Licorice dried extract abdominal pain, diarrhea, palpitations, (equivalent to 1,000mg of the herbal medicine Glycyrrhiza Radix) Colds, convulsions, joint pain, Lumbricus dried extract 150mg neuralgia, bruises, strokes, etc.

(equivalent to 600mg of the natural medicine Lumbricus)

Bellflower flower powder 600mg······· Cough, sputum, purulent diseases, tonsillitis, sore throat, empyema, e

(equivalent to 450mg of the herbal medicine Zingiberisi Radix.)

Colds, abdominal pain, diarrhea, hot flashes, etc.

Indication

Relief of various symptoms of a common cold: running nose, stuffy nose, sneezing, sore throat, cough, phlegm (sputum), chills (feeling cold due to fever), fever, headache, joint pain, and muscle pain.



Precautions

Do not take children under 12 years old.

[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 drug or its ingredients.
- (2) Patients who have experienced asthma from taking this drug or other cold remedies, antipyretic analgesics.
- (3) Children under 12 years old.
- 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.

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 physician or dentist.
- (2) Pregnant women or women suspected of being pregnant.

- (3) Baby/infants/children (under 15 years old) who have varicella (chickenpox) or influenza or are suspected of having either of them.
- (4) The elderly
- (5) Patients who have had an allergic symptom to this drug or its ingredients.
- (6) Persons with the following symptoms:

High fever, Dysuria.

(7) Persons diagnosed as having the following

Thyroid dysfunction, diabetes, heart disease, hypertension, liver disease, glaucoma, systemic lupus erythematosus, mixed connective tissue disease, respiratory dysfunction, obstructive sleep apnea syndrome, obesity.

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	
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.

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Oculomucocutaneous syndrome (Stevens-Johnson syndrome), toxic epidermal necrolysis, acute generalised exanthematous pustulosis:	skin rash/redness, small pimples (small	
Drug-induced hypersensitivity syndrome	Redness of the skin over large areas. Generalized rash, fever, feeling tired, swelling of lymph nodes (neck, armpits, groin, etc.) may appear.	
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	Symptoms, such as fever, rash, reduced urinary volume, general oedema, general malaise, arthralgia (painful joints) and diarrhea, etc. may occur.	
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.
Respiratory depression	Constipation, Shortness of breath, breathing difficulties and so may appear.

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.

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 as possible within 30 minutes after meals.

Age	One dose	Number of doses per day
adult and children 15 years and over	1 packages	3 times
children 12 years to under 15 years	2/3 packages	
children under 12 years		Do not use

[When using this product]

- (1) Please follow the recommended dosage and directions.
- (2) This medicine should be given to children only under adult supervision.

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) 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) Do not take this medicine after the expiration date.

Inactive ingredients

Lactose, aspartame, silicon dioxide, polyvinyl alcohol (partially saponified), polyvinyl alcohol/acrylic acid/methyl methacrylate copolymer, Mg stearate.

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

50 058-246-8771

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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