

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)

SHIN-VITAHAIYA PLUS AX KARYU

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

Active ingredients (in 3 packages/daily dose)	Effects
Acetaminophen 300mg.....	Antipyretic analgesic
Etenzamide 700mg	Antipyretic analgesic
Anhydrous Caffeine 75mg	Headache treatment
Dihydrocodeine phosphate 24mg.....	Anti-cough
dl-Methylephedrine hydrochloride 60mg ..	Suppress cough and sputum
Potassium guaiacol sulfonate 250mg.....	Expectorant effect (promotes airway secretion and reduces phlegm viscosity)
Chlorpheniramine maleate 7.5mg.....	Reduce sneezing, runny nose and stuffy nose
Licorice dried extract 250mg.....	Gastrointestinal weakness, fatigue, abdominal pain, diarrhea, palpitations, sore throat, peptic ulcers, swelling, drug poisoning, etc.
(equivalent to 1,000mg of the herbal medicine Glycyrrhiza Radix)	
Lumbricus dried extract 150mg	Colds, convulsions, joint pain, neuralgia, bruises, strokes, etc.
(equivalent to 600mg of the natural medicine Lumbricus)	
Bellflower flower powder 600mg.....	Cough, sputum, purulent diseases, tonsillitis, sore throat, empyema, etc.

Ginger dried extract 45mg..... (equivalent to 450mg of the herbal medicine Zingiberis Radix.)	Common cold, vomiting, loss of appetite, etc.
Cinnamon Cassia powder 150mg	Colds, abdominal pain, diarrhea, hot flashes, etc.

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 12 years old.

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 using this medicine. (Symptoms as drowsiness may occur.)

4. You should not take this medicine during breastfeeding a baby. If you want take this medicine you should avoid to breastfeed your baby.

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

6. Do not use in long-term continuously.

[Consult a doctor for the following] 

1. The following persons should consult a doctor, pharmacist, or registered salesperson 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、 Oedema、 Dysuria
- (7) Persons diagnosed as having the following
Thyroid dysfunction, diabetes, heart disease, hypertension, liver disease, Stomach and duodenal ulcer, 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, stomach discomfort
Central nervous system	Dizziness
Urology	Difficulty urinating
Others	Excessive temperature drop

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.
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.
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 urinary volume, general oedema, general malaise, arthralgia (painful joints) and diarrhea, etc. may occur.
Interstitial pneumonia	Shortness and/or difficulties of breath when go upstairs or overwork, sudden dry cough and/or fever and its continuance
Pseudoaldosteronism, myopathy	In addition to listlessness, numbness, stretched feeling, and stiffness of hands and feet, feeling of weakness and muscular pain will appear and gradually progress
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. When symptoms do not improve even after taking the medicine 5 to 6 times, stop taking this medicine and consult a physician, pharmacist or registered salesperson, being sure to take this instruction leaflet with you.

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 packages	3 times
Over 12 years old and under 15 years old	2/3 packages	
under 12 years old	Do not use	

[When using this product]

- (1) Please follow the recommended dosage and directions.
- (2) When allowing children to take the medicine, a guardian must be present to watch and tell such them how to take it.

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 want to divide one packet or take the rest, store the bag with the opening folded back and take it within 2 days.
- (5) Please do not take products that have passed the expiration date

Inactive ingredients:

Contains lactose, aspartame, silicon diacid, polyvinyl alcohol (partially saponified), polyvinyl alcohol/acrylic acid/methyl methacrylate copolymer, and 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 ☎ 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) 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.