

# 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)

## SHIN-VITAHAIYA PLUS AX JYOU

The initial symptoms of a cold include a runny and stuffy nose, followed by a cough, headache, chills, and fever. "SHIN-VITAHAIYA PLUS AX JYOU" 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.....	Antipyretic analgesic
Etenzamide 700mg .....	Antipyretic analgesic
Anhydrous Caffeine 75mg .....	Headache treatment
Dihydrocodeine phosphate 24mg.....	Anti-cough
dl-Methylephedrine hydrochloride 60mg ...	Suppress cough and sputum
Bromhexine hydrochloride 12mg .....	Antitussive expectorant
Chlorpheniramine maleate 7.5mg.....	Reduce sneezing, runny nose and stuffy nose
Licorice dried extract 250mg..... (equivalent to 1,000mg of the herbal medicine Glycyrrhiza Radix)	Gastrointestinal weakness, fatigue, abdominal pain, diarrhea, palpitations, sore throat, peptic ulcers, swelling, drug poisoning, etc.
Lumbricus dried extract 150mg .....	Colds, convulsions, joint pain, neuralgia, bruises, strokes, etc.
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 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 use in long-term continuously.

### [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) 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 medicine or its ingredients.

(6) Persons with the following symptoms :

High fever, swelling, and difficulty urinating.

(7) Persons diagnosed as having the following:

Thyroid dysfunction, diabetes, heart disease, high blood pressure, liver disease, kidney disease, gastric ulcer, duodenal ulcer, glaucoma, respiratory dysfunction, obstructive sleep apnea syndrome, obesity.

**3. 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.
Skin mucosal ocular syndrome(Stevens-Johnson syndrome) , Toxic epidermal necrolysis	Sudden high fever, sores, sore throat, extensive skin rash, redness, small pimples (small pustules) on reddened skin, general malaise, anorexia, 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 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.

4. 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

5. 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.

## Directions

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

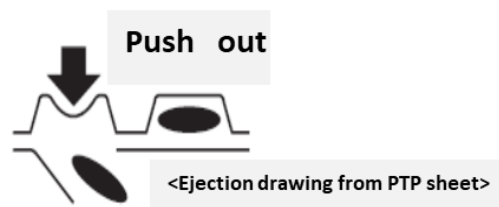
Age	One dose	Number of doses per day
Adult (15 years old and over)	3 tablets	3 times
Over 12 years old and under 15 years old	2 tablets	
under 12 years old	Do not use	

### 〈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.
- (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)
- (4) 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, silicon dioxide, 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)).

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