

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.

Cold medicine

(TABLETS)

SHIN-VITAHAIYA PLUS EX JYOU

“SHIN-VITAHAIYA PLUS EX JYOU” has antipyretic and analgesic effects, and contains “Ibuprofen” that suppresses inflammatory symptoms of the throat and nasal mucosa. It is a common cold medicine that exhibits excellent efficacy.

<i>Active ingredients (in 9 tablets/daily dose)</i>	<i>Purpose</i>
Ibuprofen 450mg	Reduce heat and reduce pain
Bromhexine hydrochloride 12mg	Antitussive expectorant
Clemastine fumarate 1.34mg	Antihistamine
Dihydrocodeine phosphate 24mg	Anti-cough
dl-Methylephedrine hydrochloride 60mg	Suppress cough and sputum
Anhydrous Caffeine 75mg	Headache treatment
Licorice dry extract 190mg	Soothe sore throat and cough
Calcium ascorbate 500mg	Vitamin C supplementation
Thiamine nitrate 25mg	Vitamin B1 supplementation
Riboflavin 12mg	Vitamin B2 supplementation

Uses

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.

Warnings

Do not use for children under 15 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) Children under 15 years old.
- (4) A pregnant woman whose infant's birth date will be within 12 weeks.

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 take overdose beyond 5 days.**

[Consult a doctor for the following]

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) Senior persons.
 - (4) A person with a medical history of being allergic to medicines and other substances.
 - (5) A person with the following symptoms:
High fever、 Dysuria
 - (6) A person 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.
 - (7) A person who has ever had following illness.
Stomach and duodenal ulcer, ulcerative colitis, Crohn's disease

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 distributor with the Japanese package insert.

Related area	Symptoms
Skin	Rash / redness, itching, blue bruise
Digestive organ	Nausea / vomiting, loss of appetite, stomach discomfort, stomach pain, stomatitis, heartburn, stomach upset, bleeding, abdominal pain, diarrhea, bloody stool
Central nervous system	Dizziness, excitement, convulsions
Circulatory system	Palpitation
Respiratory organ	Shortness of breath
Urology	Difficulty urinating
Others	Eye blur, tinnitus, swelling, nose bleeding, bleeding of gums, bleeding is difficult to stop, bleeding, back pain, excessive temperature drop, 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.
Skin mucosal ocular syndrome(Stevens-Johnson syndrome) , Toxic epidermal necrolysis	Sudden high fever, sores, sore throat, extensive skin rash, redness, etc. may persist or worsen rapidly.
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 accompany with the neck strain, and fever, nausea, vomiting etc. may occur. (Such symptoms are often reported, especially in people who are treated 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	When you breathe, the bronchus will squeeze with wheezing, whistling and a feeling of stuffiness appear.
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 distributor with the Japanese package insert.

Constipation, Thirst, Sleepiness

5. 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 the following amount with water or lukewarm water within 30 minutes after meal.

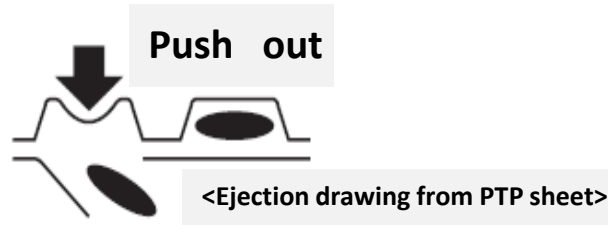
Age	One dose	Number of doses per day
Adult(15 years old and over)	3 tablets	3 times
under 15 years old	Do not use	

[When using this product]

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

Please push the projection of the PTP sheet containing tablets strongly with your fingertips as shown below, break the aluminum sheet on the back side, push out and take it.

(If you mistakenly swallow the PTP sheet as it is, it leads to an unexpected accident such as stabbing into the esophagus mucosa)



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) The fillings in the bottle is to prevent the tablets from breaking down during shipping. It will be necessary after opening, so please remove it (as to a product in bottle).
- (5) Please tighten the lid of the bottle well. Insufficient tightening may cause deterioration due to moisture (as to a product in bottle).
- (6) Do not touch the tablets with wet hands as may change the quality of the medicines due to moisture. (If water gets on the tablet, the surface may be partially melted to cause discoloration or uneven color.)
- (7) Please do not take products that have passed the expiration date

Inactive ingredients:

Lactose, Potato starch, Cellulose, Hydroxypropyl cellulose, Anhydrous calcium hydrogen phosphate, Dipotassium glycyrrhizinate, Flavors, Ethyl vanillin, Vanillin, and Partially hydrolyzed starch.

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) Although the English translation is prepared on the basis of the Japanese version of the attached document on the year and month, the attached document is revised from time to time, so the English translation may not be the latest.