

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

Allergic rhinitis medicine

(TABLETS)

Japanese Pharmacopoeia Fexofenadine hydrochloride tablets

NOSUPOL BIEN JYOU FX

Sneezing, runny nose, stuffy nose, etc. are manifested by rhinitis and sinusitis, which not only makes you feel unwell, but also makes your daily life uncomfortable, such as lack of sleep, overwork and poor concentration.

“NOSUPOL BIEN JYOU FX” is taken one tablet, twice a day, and included Fexofenadine hydrochloride which alleviates allergic symptoms caused by pollen and house dust. In addition, this is an allergy-only rhinitis medicine that makes it difficult for the mouth to become thirsty and sleepy.

Active ingredients (in 2tablets/daily dose)

Purpose

Fexofenadine hydrochloride 120mg.....

Antihistamine

Uses

Alleviation of the following nasal allergy symptoms due to pollen, house dust, etc.: Sneezing, Runny nose, Stuffy nose

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) Children under 15 years old.

2 While taking this medicine, please do not take any of the following medicines.

Other allergy medicines (including skin diseases and internal medicine for rhinitis), oral medicines containing antihistamines (cold medicine, antitussives, motion sickness, hypnosis sedative etc), antacids (aluminum hydroxide and magnesium hydroxide containing preparations), erythromycin.

- 3 Do not drink alcohol before or after taking this medicine.
- 4 You should not take this medicine during breastfeeding a baby. If you want take this medicine you should avoid to breastfeed your baby.

[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.
 - (2) A person who do not know if you have allergic rhinitis or other causes such as a cold.
 - (3) A person who have ever been diagnosed with other allergic diseases such as bronchial asthma and atopic dermatitis.
 - (4) A person having strong symptoms of stuffy nose.
 - (5) A pregnant woman or a woman suspected of being pregnant
 - (6) Senior persons.
 - (7) A person who have ever had allergic symptoms due to any medication.
- 2 The following symptoms may be adverse reactions to this medicine. If any of these symptoms occur, stop the take immediately and consult a doctor, pharmacist, or registered distributor with the Japanese package insert.

Related area	Symptoms
Skin	Swelling of throat, eyelids and/or lips, Rash, Itching, Hives, Skin redder
Digestive organ	Nausea , Vomiting, , Abdominal pain, , Indigestion
Central nervous system	Numbness, Headache, Fatigue, Dizziness, Insomnia, Irritability, Nightmare, Sleep disorder etc.
Urinary system	Frequent urination, Difficulty urinating

Others	Palpitation, Dyspepsia, Edema, Chest pain, Dyspnea, Elevated blood pressure, Menstrual abnormalities.
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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 it, skin itching, hives, faint voice, sneezing, sore throat, tightness of breath, palpitation, cloudiness of consciousness etc. appear.
Liver dysfunction	Fever, itching, rash, jaundice (yellowing of skin and white of eyes become yellow), brown urine, general fatigue, loss of appetite, etc. appear.
Agranulocytosis, leukopenia, neutropenia	Sudden high fever, chills, sore throat etc. appear.

- 3** The following symptoms may appear after taking this medicine, 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, Constipation, Diarrhea, Sleepiness.

Directions

Please take the following amount in the morning and evening.

Age	One dose	Number of doses per day
adult and children 15 years and over	1 tablet	twice
under 15 years	Do not use	

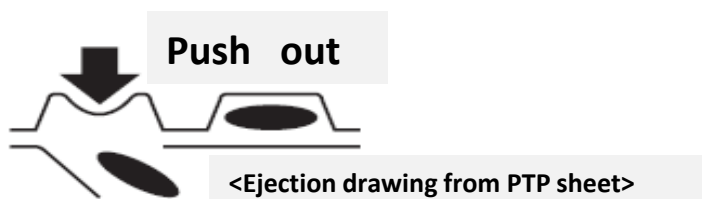
[When using this product]

- (1) Please follow the recommended dosage and directions.

- (2) When you use for seasonal allergic rhinitis occurring such as pollen, it is effective to take it from the early stage of light symptoms that begin to appear during the pollen scattering period.
- (3) You can get the effect by taking it continuously.
- (4) While you take this medicine, if symptoms do not improve after one week of use, in addition, or taking for more than 2 weeks even if symptoms are improved, please consult a doctor, pharmacist or registered distributor. In addition, please consult your doctor, pharmacist or registered drug seller if taking for more than 2 weeks even if symptoms are improved.
- (5) When using this medicine for the first time,

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) Please do not take products that have passed the expiration date.

Inactive ingredients:

Partially pregelatinized starch, Cellulose, Hydroxypropyl cellulose, Croscarmellose Na, Anhydrous silicic acid, Magnesium stearate, Pipromellose, Macrogol, Titanium oxide, Ferric oxide, Yellow ferric oxide, Carnauba wax.

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

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