

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 **Rhinitis medication for allergies** (TABLETS)

Japanese Pharmacopoeia Fexofenadine hydrochloride tablets

NOSUPOL BIEN JYOU FX

Sneezing, runny nose, stuffy nose, etc. are caused by rhinitis and sinusitis, and they not only make you feel uncomfortable and to be decreased your concentration or attention., but also make your daily life uncomfortable such as lack of sleep, overwork.

“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 ingredient Daily dose (2 tablets) of this medicine

Ingredient	Amount	Effect
Fexofenadine hydrochloride	120mg	Antihistaminic effect

Inactive ingredients

Partially pregelatinized starch, cellulose, hydroxypropylcellulose, croscarmellose sodium, silicic anhydride, magnesium stearate, pipromellose, macrogol, titanium oxide, iron trioxide, yellow iron trioxide, carnauba wax

Indication Relief of the following nasal allergy symptoms such as sneezing, runny nose, stuffy nose caused by pollen, house dust.



Precautions



When not use the product

(Failure to observe the following may result in the current symptoms worsening or adverse reactions/ accidents occurring.)

1 Do not take this medicine 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 medicines for skin diseases and oral medicines for rhinitis), oral medicines containing antihistamines (cold medicines, antitussive expectorants, motion sickness medicines, hypnotic sedatives, etc.), antacids (containing preparations of aluminum hydroxide and magnesium hydroxide), 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.

(In animal studies, it has been observed to migrate this active ingredient into mother's milk.)



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) A person who don't know if they 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) Pregnant women or women suspected of being pregnant.
- (6) The elderly
- (7) Patients who have experienced allergic symptoms associated with drugs, etc.

2. If the following symptoms are observed after taking this drug, these may be adverse reactions, so immediately discontinue the use of this medicine, and show the Japanese package insert to your physician, pharmacist, or registered salesperson for a consultation.

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.

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 be observed after taking this drug. If these symptoms persist or worsen, discontinue the use of this medicine, and show the Japanese instructions written on this package case to your physician, pharmacist, or registered salesperson for a consultation.

Dry mouth, constipation, drowsiness, blurred vision

Dosage and administration

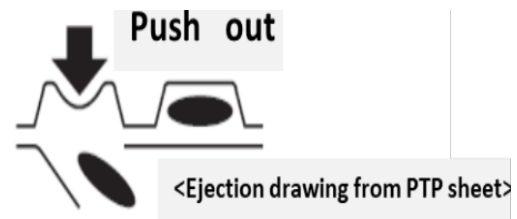
Please take the following amount in the morning and evening.

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 strictly follow the prescribed usage and dosage.
- (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 salesperson 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 on the right, 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)

Precautions for storage and handling

- (1) Store tightly closed and upright in a cool, dry place away 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

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.