Revision Sep 2020 No. 007

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

Oral remedies for persistent rhinitis

(CAPSULES)

SHIN-NOSUPOL BIEN CAPSULE

"SHIN-NOSUPOL BIEN CAPSULE" combines the particles that dissolve and show effect immediately and the particles that show effect after a certain time, so the action lasts. Therefore, it is possible to improve symptoms by taking it twice a day in the morning and evening.

Active ingredients (in 2 capsules/daily dose) Purpose

Pseudoephedrine hydrochloride 70mg Treatment for stuffy nose

d-Chlorpheniramine maleate 8mg····· Antihistamine

Belladonna Total Alkaloid 0.4mg Nasal mucus secretion regulation

Anhydrous Caffeine 100mg······ Sleepiness prevention

Uses

Alleviation of the following symptoms by acute rhinitis, allergic rhinitis or sinusitis: sneezing, runny nose (too much nasal discharge), stuffy nose, sore eyes, sore throat, headache (heavy head)

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 substances in it.
- (2) A person with the following symptoms: Dysuria due to prostatic hyperplasia.
- (3) A person diagnosed as having the following:.

 Hypertension, Heart disease, Thyroid dysfunction, Diabetes.

- 2 While taking this medicine, please do not take any of the following medicines.
 - Other internal medicines for rhinitis, containing antihistamines. (cold medicine, antitussive expectorant, motion sickness medicine, medicine for allergy etc.), gastrointestinal analgesia and spasm
- 3 Do not drive a motor vehicle or operate machinery after using this medicine. (Symptoms such as drowsiness, blurred vision, dazzling sunlight may occur)
- 4 Do not use long-term continuously.

[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 pregnant woman or a woman suspected of being pregnant.
- (3) A breastfeeding woman.
- (4) Senior persons.
- (5) A person who have ever had allergic symptoms due to any medication.
- (6) A person who has caused sleeplessness, dizziness, feeling of weakness, tremors, palpitations due to cold medicine, antitussive expectorant, internal medicine for rhinitis etc.
- (7) A person with the following symptoms:

High fever, Dysuria.

(8) A person diagnosed as having the following:.

Glaucoma, Kidney disease.

- (9) A person undergoing medical treatment with a monoamine oxidase inhibitor (such as Selegiline hydrochloride).
- 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 distributor with the Japanese package insert.

Related area	Symptoms
Skin	Rash · Redness、Itching
Digestive organ	Nausea、Vomiting、Abdominal pain、Loss of Appetite

Central nervous system	ystem Dizziness, Insomnia, Irritability, Headache, Convulsions	
Urinary system	Dysuria	
Others	Face hot flashes, Abnormal dazzling	

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 medicine, itching of the skin, urticarial, hoarseness of voice, sneezing, throat itching, breathing, palpitations, turbulence of consciousness etc. appears.
Skin mucosal ocular syndrome(Stevens-Johnson syndrome), Toxic epidermal necrolysis, Acute generalized rash pustular disorder.	High fever, congestion of eyes, rash, sore lips, sore throat, extensive rash / redness of the skin, small bumps (small blisters) on reddened skin. Whole body may become heavy. There is no appetite, etc. will persist or suddenly worsen.
Aplastic anemia	Bruises, nasal bleeding, gingival bleeding, fever, skin and mucous membranes pale, fatigue, palpitations, shortness of breath, mood deterioration, hematuria, etc.
Agranulocytosis	Sudden high fever, chilling, sore throat etc. 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 distributor with the Japanese package insert.

Thirst, sleepiness, constipation and blurred eyes.

4 If these symptoms do not improve after having used this medicine 5 or 6 times, stop taking the medicine, and consult a doctor, pharmacist, or registered distributor with the Japanese package insert.

Directions

Please take the following amount in the morning and evening.

Age	One dose	Number of doses per day
adult and children 15 years old and over	1 capsule	twice

children under 15 years old.	Do not use
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[When using this product]

- (1) Please follow the recommended dosage and directions.
- (2) When using this medicine for the first time,

Please push the projection of the PTP sheet containing capsules 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)

Push out

<Ejection drawing from PTP sheet>

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

	Corn starch, Lactose, Cellulose,
	Hydroxypropyl cellulose, Carmellose Ca, Ethyl
Inactive ingredients:	cellulose, Glycerin fatty acid ester, Talc,
_	Gelatin in the capsule body, and Sodium lauryl
	sulfate.

Questions or comments

If you have any suggestions about this product, please contact the shop you purchased or the following address.

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.
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