

この説明書は製品についての参考情報です。正しくは製品に記載されている説明をご確認ください。

This document serves as reference information. Please ensure to read the information provided with the product.

[Keep this information leaflet with this medication and be sure to read it before taking the medication.]

ALESION® 20

Class 2 OTC drug

Medication for Allergies Epinastine Hydrochloride Product

- Each **ALESION 20** tablet contains 20 mg of epinastine hydrochloride, a second-generation antihistamine, as the active ingredient. ALESION 20 exerts excellent effects on allergy symptoms of sneezing and nasal discharge.
This is an oral medication for allergic rhinitis containing the active ingredient of epinastine hydrochloride, a second-generation antihistamine, which is unlikely to cause heavy drowsiness.
- Rhinitis symptoms due to pollen or house dust occur when any causative substances (allergens), such as histamine and leukotriene, are inhaled and released in the body. Epinastine hydrochloride inhibits the action of such allergens and suppresses their release itself, thereby exerting excellent effects on allergic rhinitis symptoms.
- A once-daily dose taken at bedtime is most effective. If ALESION 20 is used for seasonal allergic rhinitis symptoms due to pollen or such, it works most effectively when taken soon after symptoms begin to appear.

⚠ Precautions for Use

❌ Contraindications

(If you do not follow the precautions exactly as listed below, your current symptoms may worsen and you may be placed at increased risk of side effects or the risk of having some accidents.)

- The following persons must not take this medication:**
 - Persons who have had an allergic reaction to any of the ingredients of ALESION 20.
 - Children under 15 years of age.
 - Persons who have received a diagnosis of the following diseases: Liver diseases
- Do not take any of the following medications during the period of taking ALESION 20:**
Other anti-allergic medications (including medications for skin diseases and oral medications for rhinitis), oral medications containing antihistamines (e.g., common cold medications, antitussive-expectorant medications, motion sickness medications, hypnotic sedatives)
- Do not operate vehicles or machinery after taking this medication.**
(Sleepiness or such may occur.)
- Breast-feeding women are advised not to take ALESION 20 or to stop breast-feeding if this medication is to be taken.**
- This medication must not be taken soon before or soon after alcohol intake.**



Consultation

- The following persons should consult a physician, pharmacist, or registered salesperson before taking this medication:**
 - Persons who are receiving any treatment from a physician.
 - Women who are or may be pregnant.
 - Elderly persons.
 - Persons who have had any allergic reactions to drugs or other substances.
 - Persons whose symptoms have not been confirmed to be related to allergies or to any other causes.
 - Persons who have received a diagnosis of any other allergic diseases such as bronchial asthma and atopic dermatitis.
 - Persons who are switching a medication containing 10 mg of epinastine hydrochloride to ALESION 20.
- If any of the symptoms listed below develop after taking ALESION 20, they might be side effects of the medication. Stop taking this medication immediately and consult a physician, pharmacist, or registered salesperson, presenting this leaflet.**



Affected area	Symptoms
Skin	Rash/redness, swelling, itching
Gastrointestinal	Nausea/vomiting, stomatitis, stomach discomfort, abdominal pain, stomach heaviness, heavy feeling in the stomach, bloating, inappetence
Neuropsychiatric	Dizziness, sleeplessness, headache, fuzzy head, numbness, nightmare, hallucinations, auditory hallucination
Respiratory	Respiratory distress
Cardiovascular	Palpitations
Urinary	Dysuria, pollakiuria, hematuria, proteinuria
Other	Swelling, hot flush, chest pain, sputum sticking, malaise, nasal stuffiness, abnormal menstruation, bitter taste, taste diminished, gynecomastia (enlarged breasts in men), breast enlargement

(Continued on the reverse side)

(Continued from the front side)

In rare cases, any of the serious symptoms listed below may occur. In such cases, immediately consult a physician.

Name of symptoms	Symptoms
Hepatic impairment	Fever, itching, rash, jaundice (yellowing of the skin and whites of the eyes), brown urine, general malaise, inappetence or such occurring.
Decreased platelets (thrombocytopenia)	Bleeding symptoms such as nasal bleeding, gingival bleeding, and bruising occurring due to a decrease in platelet count (platelets are blood components).



- **Any of the conditions mentioned below may occur after taking ALESION 20. If such symptoms persist or worsen, stop taking this medication and consult a physician, pharmacist, or registered salesperson, presenting this leaflet.**
Thirst, constipation, diarrhea, sleepiness
- **If there is no alleviation of allergy symptoms after taking this medication for about a week (including taking other drugs containing epinastine hydrochloride during this time), stop taking all epinastine hydrochloride medications and consult a physician, pharmacist, or registered salesperson, presenting this leaflet.**
- **If ALESION 20 or other medications containing epinastine hydrochloride are taken for more than 2 consecutive weeks even after allergy symptoms have been alleviated, consult a physician, pharmacist, or registered salesperson for advice.**

Indications

Alleviation of the following symptoms of nasal allergies caused by pollen, house dust or other allergens: Nasal discharge, nasal stuffiness, and sneezing

Dosage and Administration

Take a dose of ALESION 20, according to the table below, with cold or lukewarm water, once daily at bedtime.

Age	Adults (aged 15 years or older)	Children under 15 years of age
Dose	 1 tablet	 This medication must not be taken.

<Precautions concerning Dosage and Administration>

- (1) ALESION 20 must be used strictly in accordance with the specified dosage and administration.
- (2) If this medication is used for symptoms of seasonal allergic rhinitis due to pollen or other allergens, it is most effective when taken from the predicted start date of pollen dispersal or soon after symptoms begin to appear.
- (3) How to remove the tablet

As shown in the illustration on the right, firmly press the raised portion of the press-through package (PTP) with a fingertip to push the tablet through the aluminum foil on the reverse side. (If the PTP sheet is mistakenly swallowed, its sharp edges may perforate the esophageal mucosa or lead to incidental events.)



(Illustration showing removal of the tablet from the PTP sheet)

Ingredients

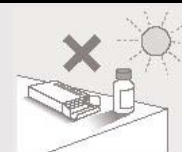
Epinastine hydrochloride 20 mg

in 1 tablet (the daily dose)

Excipients: Anhydrous silicic acid, lactose, hypromellose, povidone, ethyl acrylate-methyl methacrylate copolymer, macrogol, silicone resin, magnesium stearate, talc, titanium oxide, corn starch

Precautions for Storage and Handling

- (1) Store in a dry, cool place away from direct sunlight.
- (2) Keep out of the reach of children.
- (3) Do not transfer the contents to another container (which may lead to drug misuse or changes in the quality of this product).
- (4) Do not take this medication after the expiration date.

**Contact Information**

Inquiries should be made to the drugstore where you purchased the product or to the customer service office. Customer Service Office, SSP Co., Ltd. Phone 0120-028-193
Opening hours: 9:00 to 17:30 (closed on Saturdays, Sundays, and Japanese public holidays)



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