

Please read the instructions carefully before using.

アレジオン®20

花粉・アレルギー性鼻炎には 第2類医薬品



ALESION20

Class 2 OTC drug

Allergy Medicine Epinastine Hydrochloride Product

<Product Features>

- ALESION20 contains 20 mg of epinastine hydrochloride, the second generation antihistamine ingredient, per tablet. It works effectively for symptoms such as sneezing and nasal discharge. Since it contains a second generation antihistamine ingredient, it is an oral medicine for allergic rhinitis that is less likely to cause drowsiness.
- Rhinitis symptoms due to pollen and house dust occur resulting from the release of the causative substances such as histamines and leukotrienes after breathing in these dusts. Epinastine hydrochloride works effectively for allergic rhinitis symptoms by inhibiting the action of causative substances and suppressing the release itself.
- Once daily dosing before bedtime is effective. In addition, if this drug is used for seasonal allergic rhinitis symptoms such as hay fever, it is effective to take the drug early on at the sign of symptoms.

CAUTIONS FOR USE

CONTRAINDICATIONS

(Failure to observe the following may cause the present symptoms to worsen or produce adverse drug reactions and/or accidents.)

1. The following people must not take this drug:

- (1) Those with a previous allergic reaction to this drug or ingredients of the drug
- (2) Children under 15 years of age
- (3) Those who were diagnosed with the following disease: Liver disease

2. Do not take any of the following drugs while taking this drug.

Other anti-allergic drugs (including drugs for skin disease and internal medicines for rhinitis), oral medicines containing antihistamines (e.g. cold medicines, expectorants, motion sickness drugs, sedative-hypnotics, etc.)

3. Do not drive or operate machinery after taking this drug.

(Sleepiness, etc. may occur.)

4. For those who are breastfeeding, do not take this drug or avoid breastfeeding while taking this drug.

5. Do not drink alcohol before and after taking this drug.

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WHEN to consult a doctor

1. The following people should consult a doctor, pharmacist or registered salesperson before taking this drug:

- (1) Those who are under treatment by a doctor
- (2) Pregnant women or those who may become pregnant
- (3) Elderly people
- (4) Those with any previous allergic reactions to drugs or other things
- (5) Those whose symptoms are not differentiated between allergic symptoms and symptoms due to other causes.
- (6) Those who were diagnosed with other allergy disease such as bronchial asthma and atopic dermatitis
- (7) Those who are planned to switch from the medicine containing 10 mg of epinastine hydrochloride to this drug

2. The following symptoms may be adverse drug reactions. If any of these symptoms occur, STOP TAKING the drug immediately and consult a doctor, pharmacist or registered salesperson. Show them this leaflet.

Related areas	Symptoms
Skin	Rash, redness, swelling or itching
Digestive system	Nausea, vomiting, oral ulcer, stomach discomfort, abdominal pains, stomach heaviness, heavy stomach feeling, abdominal fullness or loss of appetite
Central nervous system	Dizziness/vertigo, loss of sleep, headache, foggy head, numbness, nightmares, hallucinations or auditory hallucinations
Respiratory system	Breathlessness
Circulatory system	Palpitations
Urinary system	Urination difficulties, frequent urination, bloody urine or protein urea
Other	Swelling, hot flashes, chest pain, sputum sticking sensation, malaise, congested nose, abnormality in menstruation, bitter taste in mouth, diminished sense of taste, gynecomastia (excessive development of the breasts in males) or mastoplasia

In rare cases, the following serious symptoms could occur. In such an event, immediately consult a doctor.

Symptom's name	Symptoms
Liver dysfunction	Fever, itching, rash, jaundice (skin and whites of the eyes turn yellow), brown urine, general malaise, loss of appetite, etc. may occur.
Thrombopenia	Hemorrhagic symptoms such as nose bleeding, gum bleeding and purpura may occur, caused by reduced counts of platelets which is a component of the blood.

3. You may develop the following symptoms after taking this drug. If the symptoms continue or worsen, stop taking the drug and consult a doctor, pharmacist, or registered salesperson. Show them this leaflet.
Dry mouth, constipation, diarrhea or drowsiness
4. If the symptoms do not improve after about one week (including the duration of drugs containing other epinastine hydrochloride), stop taking this drug and consult a doctor, pharmacist or registered salesperson. Show them this leaflet.
5. If you take this drug for more than 2 weeks even after improvement of the symptoms (including the duration of other drugs containing epinastine hydrochloride), consult a doctor, pharmacist or registered salesperson.

Indications

Alleviation of the following allergic rhinitis symptoms due to pollen, house dust (indoor dust), etc.: Runny nose, nasal congestion and sneezing

Dosage and Directions

Take the following dose once daily before bedtime with either cold or lukewarm water.

Age	Adult (15 years or over)	Under 15 years
One dose	1 tablet	Do not take

<Cautions regarding dosage and directions>

- (1) Strictly observe the dosage and directions.
- (2) If this drug is used for seasonal allergic rhinitis symptoms such as hay fever, it is effective to start taking the drug from the predicted date of pollen dispersion or early on at the sign of symptoms.
- (3) Removing a tablet from blister pack:

As shown in the figure on the right, push firmly on the blister until the tablet pierces the seal on the reverse side, then remove the tablet (Taking the tablet without removing it from the blister pack may cause esophageal mucosal injury).



Ingredients

One tablet (recommended daily adult usage) contains:

Epinastine Hydrochloride - 20 mg

Additives

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

Storage and Handling Cautions

- (1) Store this drug in a cool, dry place away from sunlight and moisture.
- (2) Keep out of reach of children.
- (3) Do not transfer this drug to a different container (It may cause misuse or deterioration of quality).
- (4) Do not use this drug after the expiration date.



The marketing of this drug has been approved for domestic sales in accordance with the Japanese Pharmaceutical and Medical Devices Act (PMD Act.)