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2nd Class OTC drug

Please read the package insert carefully before use and keep it with this medicine.

Japanese Pharmacopoeia Ebastine Tablets

Allergic rhinitis medicine

エバステルAL

EBASTEL AL

Precautions for use

To be avoided

(Failure to follow the directions below may worsen existing symptoms or increase the risk of adverse reactions/accidents)

1. Do not use if you:

- (1) Have had an allergic reaction to this medicine or any of its ingredients.
- (2) Are children under 15 years of age.

2. Do not use any of the following medicines while taking this medicine.

Other allergy medicines (including medicines for skin diseases and oral medicines for rhinitis), oral medicines, etc. containing antihistamine (cold medicines, antitussives and expectorants, motion sickness medicines, hypnotics and sedatives, etc.)

3. Do not drive or operate machinery after use.

(Sleepiness, etc. may occur.)

4. Do not use during breastfeeding; avoid breastfeeding when using this medicine.

(Medicine penetration into breast milk is observed in animal studies.)

5. Do not drink alcohol before and after use.

What to ask a doctor, pharmacist or registered salesperson

1. Ask a doctor, pharmacist or registered salesperson before use if you:

- (1) Are currently treated by a doctor.
- (2) Are pregnant or may possibly be pregnant.
- (3) Are elderly.
- (4) Have ever had allergic reaction to any medicines, etc.
- (5) Have been diagnosed with the following conditions:
Liver disorder, bronchial asthma, atopic dermatitis
- (6) Have any symptoms whose cause is unclear as to whether it is allergy related or related to another cause.

2. The following symptoms, occurred due to this medicine, may be observed as adverse reactions. If any of the symptoms occur after use, stop use immediately and ask a doctor, pharmacist or registered salesperson with the package insert.

Related area	Symptom
Skin	Rash/redness, itching
Digestive organs	Nausea/vomiting, stomach distress, abdominal pain, glossitis
Psychoneurotic system	Dizziness, insomnia, headache, malaise, numbness
Circulatory organs	Palpitation, blood pressure increased
Urinary organs	Dysuria, pollakiuria, urinary sugar
Others	Swelling, hot flush, nasal dryness, chest oppression, weight increased, menstruation disorder, hair loss, dysgeusia

(Continued overleaf)

The following serious symptoms may rarely occur. In such cases, ask a doctor and receive medical treatment immediately.

Name of symptom	Symptom
Shock (anaphylaxis)	Symptoms such as itchy skin, hives, hoarseness, sneezing, itchy throat, difficulty in breathing, palpitation and clouding of consciousness may occur immediately after use.
Liver disorders	Symptoms such as fever, itching, rash, jaundice (the skin and whites of eyes becoming yellow), brown urine, general malaise, loss of appetite may occur.

3. The following symptoms may occur after use; in case these symptoms persist or worsen, stop use and ask a doctor, pharmacist or registered salesperson with the package insert.


Dry mouth, sleepiness, diarrhea

Indications

Relief of the following nasal allergy symptoms caused by pollen, house dust, etc.: Runny nose, nasal congestion, sneezing

Dosage/directions

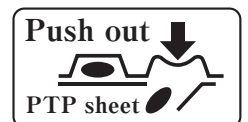
Take the tablets with room temperature or warm water at bedtime.

Age	One dose	Daily dose
Adults (15 years and older)	1 tablet 	Once
Children (Under 15 years of age)	✗ Do not use.	

<Precautions for dosage/directions>

- (1) Follow the dosage/directions.
- (2) When the medicine is used for the symptoms of seasonal allergic rhinitis caused by pollen, etc., it is effective to use the medicine from an early stage when the symptoms are mild or when the symptoms begin to appear in the pollen dispersal period.
- (3) If symptoms do not improve after using for about one week, ask a doctor, pharmacist or registered salesperson with the package insert. If the medicine is used for longer than two weeks after improvement of symptoms, ask a doctor, pharmacist or registered salesperson with the package insert.
- (4) How to take out tablets:

As shown on the right, strongly press the convex part of the PTP sheet with your finger tip to break the aluminum foil on the back and take out a tablet. (Accidental swallowing the PTP sheet may cause an unexpected accident, such as esophageal mucosa penetration, etc.)



Ingredients/contents (in 1 tablet)

Ingredients/contents
Ebastine 5 mg

[Inactive ingredients] Lactose, cellulose, hydroxypropyl cellulose, carmellose calcium, magnesium stearate, silicic anhydride, hypromellose, macrogol, titanium oxide, talc

Precautions for storage and handling

- (1) Store in a cool and dry place avoiding high temperatures, humidity, and direct sunlight.
- (2) Keep out of reach of children.
- (3) Do not transfer the product to another container. (It may cause misuse and deterioration in the quality.)
- (4) Store and handle this product carefully so as not to break the aluminum foil of the PTP sheet or to damage the tablets inside.
- (5) Do not use this product after its validity date has expired (printed on the outer box).

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