Ophthalmic medication for allergies only.

# Mytear<sub>®</sub> ALPITATTO EX $\alpha$

Category 2 OTC medicines



#### 1. Confirm your symptoms

This medicine is Ophthalmic medication for allergies only and effective for "Relief of the following allergy symptoms in the eyes caused by pollen, house dust, etc.: Conjunctival hyperemia, itchy eyes, blurred vision (eye mucus), teary eye, foreign body sensation (gritty sensation)".

[Hyperemia, itching, blurred vision, etc. occur due to various causes. This medicine is effective for these symptoms caused by allergy.]

### 2. Follow the instruction on dosage and directions

Apply 1 to 2 drops at a time, 4 times a day.

#### 3.What you should not do

### 1. The following persons should not use this medicine:

(1) Children under 7 years

【The safety of this medicine in children under 7 years has not been established. Do not use this medicine for children under 7 years.】

(2) Women who are or may be pregnant

[The safety of this medicine during pregnancy has not been established. Do not use this medicine for women who are or may be pregnant.]

(3) Women who are breastfeeding

【The safety of this medicine during lactation has not been established. Do not use this medicine for women who are breastfeeding.】

# 2. Do not operate vehicles or machines if you use this medicine with nasal drops.[Sleepiness may appear.]

#### 4.Who should seek consultation

# 1. The following persons should consult a physician, pharmacist, or registered salesperson before using this medicine:

(1) Persons under treatment by a physician

【This medicine may have an effect on medicines prescribed by the physician. Prescribed medicines may contain the same ingredient as that contained in this medicine.】

(2) Persons under treatment of allergy such as hyposensitization therapy

[Medicines used in the treatment may contain the same ingredient as that contained in this medicine. This medicine may have an effect on the treatment.]

(Hyposensitization therapy: An extract of substance which can cause allergic symptoms (e.g., cedar pollen for pollinosis) is administered at low doses for a long period to gradually build a tolerance to an allergic substance and prevent hypersensitivity.)

(3) Persons who have had allergies to medicines or something

[Persons who have had allergic symptoms such as rash or redness, itching, etc. to medicines in the past should use this medicine with caution. Allergies may be caused by use of the medicines which were used at the time of past allergies or other medicines similar to those.]

(4) Persons who have suffered from the following symptom:

Severe eye pain

[Severe eye pain may be caused by acute glaucoma, corneal ulcer, other disease or trauma. These symptoms require appropriate treatment by physician.]

(5) Persons diagnosed with the following condition:

Glaucoma

[Glaucoma may be associated with blurred vision. This medicine has no therapeutic effect on glaucoma. Glaucoma requires appropriate treatment by physician.]

(6) Persons who do not know whether their symptoms are caused by allergy or by other causes.

Especially, persons in the following cases should consult a physician before using this medicine, because you cannot judge if the symptoms are due to allergy:

- If you have symptoms in only one eye.
- If you have symptoms in only the eyes and not in the nose.

If your eyesight is affected.

[Treatment may be delayed if you continue to use this medicine for symptoms caused by other than allergies without specific therapeutic purpose.]

## Be sure to read this leaflet before you use this medicine.

### 4.Who should seek consultation

2. Stop using this medicine immediately and consult a physician, pharmacist, or registered salesperson if the following symptoms appear after using this medicine because they might be side effects of the medicine. Take the leaflet inserted in the package with you.

Affected area	Symptoms
Skin	Rashes, redness, itching
Eye	Hyperemia, itching, swelling (including around the eyes), irritation, pain, foreign body sensation, watery eyes, eye mucus
Others	Breathing difficulties

[The above symptoms may appear in some persons following the use of this medicine. Stop using this medicine if the above symptoms appear and consult a physician, pharmacist, or registered salesperson to receive instructions.]

In rare cases, serious symptoms might occur. In such a case, immediately consult a physician.

Name of the symptom	Symptoms
Anaphylaxis	Symptoms such as breathing difficulties, edema (for example,
	swelling of the throat, eye lids, nasal membrane, and lips), and urticaria
	appear soon after using this medicine.

[The above symptoms may rarely appear in some persons following the use of this medicine. Stop using this medicine immediately if the above symptoms appear and consult a physician to receive medical care.]

# Stop using this medicine immediately and consult a physician, pharmacist, or registered salesperson in the following cases. Take the leaflet inserted in the package with you.

(1) If your symptoms have worsen.

[Other disease can be considered as an alternative cause.]

(2) If there is no improvement in your blurred vision. (You may have other disease such as glaucoma.) [Glaucoma, cataract, corneal disorder, retinopathy or other disease can be considered as an alternative cause.]

(3) If there is no improvement in your symptoms after using this medicine for 2 days.

[Other disease can be considered as an alternative cause if there is no improvement in your symptoms after using this medicine for 2 days. The symptoms may be aggravated if you leave them without any improvement and continue this medicine.]

#### 4.Who should seek consultation

(4) If you use this medicine for more than 2 weeks even after there is an improvement.

[You should not use this medicine without specific therapeutic purpose. You should consult a physician, pharmacist, or registered salesperson if you use for more than 2 weeks.]

%Not all the adverse reactions appear soon after starting medicine; some reactions appear after the long term use.
Caution should be exercised for the symptoms listed in the precautions, such as "Skin: Rashes, redness, etc.", "Eye:
Hyperemia, itching, etc.", "Others: Breathing difficulties". Instruct the patient to stop using this medicine immediately if
these symptoms appear and to consult a physician, pharmacist, or registered salesperson.

### 5. Precautions regarding dosage and directions

1. Children are permitted to use this medicine only under the direction and supervision of a parent or other responsible adult.

(Do not use this medicine for children under 7 years.)

[This medicine should be properly used under direction and supervision of a parent or

other responsible adult to avoid misuse by children.]

# 2. Do not touch the tip of the bottle to your eye, eyelid, or eye lashes when you apply drops to your eye. In addition, do not use a clouded solution.

(Medical solution may be contaminated or clouded if eye mucus or other foreign body,etc. gets into the tip of the bottle.)

[Medical solution may be contaminated by eye mucus, etc. You should not touch the tip of bottle when you apply drops. You should not use a clouded solution as it may be contaminated.]

# 3. Do not use this medicine while wearing contact lenses.

# (Take off your contact lenses once and apply.)

(Wear contact lenses 5 or more minutes after application of this medicine when you wear them again.) [Effect of any ingredient of this medicine on contact lenses has not been clarified. You should not apply this medicine while wearing contact lenses.]

Be sure to read the leaflet (Translated from Japanese package insert on web site) when you use this medicine. It describes important precautions in addition to the contents of this document.