

## Disclaimer

- This product is a pharmaceutical product approved under a Japanese law, the Law for Ensuring the Quality, Efficacy and Safety of Drugs and Medical Devices, with a view to its sale and use in Japan.
- Multilingual product information is a translation of the product labeling written in Japanese and provided for your information only. It does not warrant that its contents and the product itself conforms to laws and regulations in countries other than Japan.
- Multilingual product information is a tentative translation by Our Company, and may be modified or altered without notice.
- Our Company assumes no responsibility for any occurred problem attributable to the contents of the multilingual product information.

# Sante Medical 12<sup>®</sup>

## Precautions for use



### Consultation

1. The following people should consult with their doctor, pharmacist, or registered pharmaceutical distributor before using this product.
  - (1) People receiving treatment from a doctor
  - (2) People who have experienced an allergic reaction to medicine or other substances
  - (3) People who have the following symptom  
Severe pain in the eyes
  - (4) People who have received the following diagnosis  
Glaucoma
2. If you experience any of the following symptoms after using this product, it may be an adverse reaction. In such a case, please stop using the product immediately, take this information form to your doctor, pharmacist, or registered pharmaceutical distributor and seek consultation.

Area affected	Symptom
Skin	Rash/redness, itchiness
Eye(s)	Redness, itchiness, swelling, stinging pain

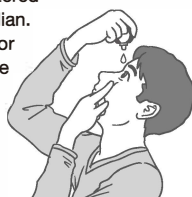
3. In any of the following cases, please stop using the product, take this information form to your doctor, pharmacist, or registered pharmaceutical distributor and seek consultation.
  - (1) If blurriness of the eyes does not improve
  - (2) If symptoms do not improve within 5 to 6 days of use

## Dosage / Administration

Instill 1 to 3 drops at a time, 5 to 6 times daily.

### • Please observe the following precautions.

- (1) Overuse can cause sensations of excessive brightness and may actually lead to red eyes.
- (2) If administered to a child, the product must be administered under the direction and observation of the child's guardian.
- (3) Do not let the tip of the bottle touch your eyes, eyelids or eyelashes (doing so could cause the solution to become contaminated with eye mucus or bacteria). Do not use the product if it does become contaminated.
- (4) Do not use the product while wearing soft contact lenses.
- (5) Use only as an eye drop.



## Indication

Tired eyes, conjunctival congestion, bleary eyes (increase in eye mucus, etc.), itchy eyes, prevention of eye disease (after swimming, when dust or sweat enters the eyes, etc.), blepharitis (soreness of eyelids), ophthalmia due to light rays such as ultraviolet rays (e.g., snow blindness), discomfort while wearing hard contact lenses

## Ingredients and quantity

Ingredients	Quantity	Action
Vitamin B <sub>12</sub> (cyanocobalamin)	0.02%	Relieves eyestrain by revitalizing the ciliary muscles.
Neostigmine methyl sulfate	0.005%	Improves conditions such as tired eyes by improving the focus adjustment mechanism of the eyes.
Chondroitin sulfate sodium	0.5%	Protects the cornea and moisturizes the eyes by preventing evaporation of tears.
Vitamin B <sub>6</sub> (pyridoxine hydrochloride)	0.05%	Activates cell metabolism of eye tissue.
Panthenol	0.05%	Activates cell metabolism of eye tissue.
Potassium L-aspartate	0.5%	Increases tissue respiration in the eyes.
Taurine	0.5%	Activates cell metabolism of eye tissue.
Chlorpheniramine maleate	0.03%	Suppresses inflammation and itchiness of the eyes by suppressing histamine activity.
Epsilon-aminocaproic acid	1.0%	Suppresses production of substances that cause inflammation.
Dipotassium glycyrrhizinate	0.1%	Suppresses inflammation of the eyes.
Zinc sulfate hydrate	0.05%	Suppresses inflammation of the eyes with its astringent action.
Tetrahydrozoline hydrochloride	0.03%	Suppresses congestion of the conjun (the whites of the eyes).

This product contains the following excipients: edetate sodium hydrate, chlorobutanol, sodium hyaluronate, benzalkonium chloride, boric acid, d-borneol, l-menthol, isotonicizing agent, and pH-adjusting agent.

### [Precautions regarding ingredients and quantity]

You may experience a sweet taste in your mouth after putting the drops in your eyes. This is due to one of the active ingredients, dipotassium glycyrrhizinate, passing into your mouth through the lacrimal ducts. It is not due to degradation of quality or any other abnormalities of the product.

## Precautions regarding storage and handling

- (1) Store in a cool place away from direct sunlight and keep sealed. To preserve the quality of the product, do not leave it in a hot place such as inside a car or near a heater. If the product is left in a hot place, the bottle may become warped causing the solution to leak and degrading its quality. Please do not use the product in such a case.
- (2) Keep out of reach of children.
- (3) Do not transfer the solution to another receptacle. (Doing so may lead to misuse of the product or may affect its quality.)
- (4) Do not share the product with another person.
- (5) Do not use the product if it has exceeded its use-by date. Even before the use-by date, please use the product as soon as possible after opening the bottle.
- (6) Depending on the conditions of storage, the ingredients may crystallize and form red deposits around the inside of the bottle's tip or on the inside of the cap. If this occurs, gently wipe off the deposits with a clean piece of gauze before using the product.
- (7) The product's red color is due to the vitamin B<sub>12</sub> ("red vitamin" cyanocobalamin) in the solution. If you spill any of the solution and stain your clothes when using the product, immediately wash your clothes with water.

