

## 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 Plus 12<sup>®</sup>

## Precautions



### Consultation

**1. The following persons should contact a physician, pharmacist, or registered salesperson for a consultation before use.**

- (1) Patients undergoing medical treatment from a physician
- (2) Patients who have experienced allergic symptoms associated with drugs, etc.
- (3) Persons with the following symptoms:  
Severe eye pain
- (4) Persons diagnosed as having the following:  
Glaucoma

**2. If the following symptoms are observed after using this medicine, these may be adverse reactions, so immediately discontinue the use, and show this document to your physician, pharmacist, or registered sales person for a consultation.**

Area affected	Symptom
Skin	Rash/redness, itching
Eyes	Congestion of the eye, itching, swelling, stinging pain

**3. In case of the following, stop taking this medicine and consult a physician, pharmacist or registered salesperson, being sure to take this instruction leaflet with you.**

- (1) When blurred vision does not improve
- (2) When symptoms do not improve even after using the medicine for 5 to 6 days.

## Dosage and Administration

Use 1 to 3 drops of this medicine at a time 5 to 6 times a day.

### • Please observe the following precautions.

- (1) Excessive use may cause abnormally brightness or eye congestion.
- (2) When allowing children to use the medicine, a guardian must be present to watch and tell such them how to use it.
- (3) Ensure that the tip of the container does not touch your eyes, eyelids or eyelashes (doing so could cause the solution to become contaminated with eye mucus or bacteria). Do not use when the medicine appears cloudy.
- (4) Do not use this medicine while wearing soft contact lenses.
- (5) Use this medicine only for ophthalmic instillation.



## Indication

Eyestrain, conjunctival congestion, blurred vision (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

## Ingredient and amount

Ingredients	Quantity	Action
Natural vitamin E (d-α-tocopherol acetate)	0.025%	Improves blood flow in peripheral vessels.
Vitamin B <sub>12</sub> (cyanocobalamin)	0.02%	Relieves eyestrain by revitalizing the ciliary muscles.
Neostigmine methyl sulfate	0.005%	Improves conditions such as eyestrain 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.
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	0.25%	Suppresses inflammation of the eyes.
Zinc sulfate hydrate	0.05%	Suppresses inflammation of the eyes with its astringent action.
Tetrahydrozoline hydrochloride	0.05%	Suppresses congestion of the conjunctiva (the whites of the eyes).

This product contains the following excipients: edetate sodium hydrate, sodium hyaluronate, benzalkonium chloride, boric acid, polyoxyethylene hardened castor oil, polysorbate 80, BHT, d-borneol, l-menthol, isotonizing agent, and pH-adjusting agent.

### [Precautions relating to ingredient and amount]

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 for 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 vials 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 medicine to a different container. (It may lead to misuse or alter the quality of the medicine.)
- (4) Do not share the product with others.
- (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.

