Product information

[Drug Facts]



Please be sure to read this product information carefully before use. Keep this product information in a safe place so that you can read again, when you need it.

Cold Medicine

(SYRUPS)

NOSUPOL KODOMO KAZE SYRUP S

"NOSUPOL KODOMO KAZE SYRUP S" is a cold medicine for children which contains Licorice extract and Bellflower flow extract from the crude drugs, in addition 5 kinds of active ingredients such as acetaminophen, dextromethorphan hydrobromide hydrate etc.

The function of the active ingredients relieves symptoms such as fever, sore throat, cough, phlegm, runny nose, stuffy nose, etc. occurred in child who tend to be exhausted by colds.

Active ingredients (in 60 mL/Maximum daily Purpose dose)				
Acetaminophen	300mg***********************************	Antipyretic analgesic		
Chlorpheniramine maleate 2.4mg·······		Reduce sneezing, runny nose and stuffy nose		
Dextromethorphan hydrobromide hydrate 16mg·•		Reduce cough		
dl-Methylephedrine hydrochloride 16mg····		Bronchodilator		
Anhydrous caffein	e 32mg·····	Reduce headache		
Licorice extract	50mg·····	Soothe sore throat and cough		
Bellflower flower extract 0.24mg·····		Easier to expectorate phlegm		
Uses	Relaxation of various symptoms of colds (runny nose, stuffy nose, sneeze, sore throat, cough, sputum, chills, fever, headache, joint pain, muscle pain)			
Warnings	* In spite of this medicine for children, it describes the general precautions specified as a cold medicine.			
[To be avoided]				

(Failure to observe the following may result in the current symptoms worsening or adverse reactions/ accidents occurring.)

- 1. Do not take to the following person:
- (1) A person with a medical history of being allergic to this medicine or similar components in this medicine.
- (2) A person who have ever had asthma after taking this medicine or other cold medicine, antipyretic analysis.
- 2. While taking this medicine, please do not use any of the following medicines.

Other medicines for cold, antipyretic analgesics, sedatives, antitussive expectorants, and internal medicines containing antihistamine etc. (internal medicine for rhinitis, motion sickness medicine, allergy medicine etc).

- 3. Do not drive the car or operate the machine after taking this medicine. (Symptoms such as sleepiness may occur)
- 4. Do not drink alcohol before or after taking this medicine.
- 5. Do not use in long-term continuously.

[Consult a doctor for the following]

- 1 The following persons should consult a doctor, pharmacist, or registered distributor before using this medicine.
- (1) A person undergoing medical treatment from a doctor or dentist.
- (2) A pregnant woman or a woman suspected of being pregnant
- (3) A woman with breastfeeding.
- (4) A person who have ever had allergic symptoms due to any medication.
- (5) A person with the following symptoms:

High fever, Dysuria

(6) A person diagnosed as having the following:.

Thyroid dysfunction, diabetes, heart disease, hypertension, liver disease, kidney disease, stomach / duodenal ulcer, glaucoma.

2 The following symptoms may be adverse reactions to this medicine. If any of these symptoms occur, discontinue take immediately and consult a doctor, pharmacist, or registered distributor with the Japanese package insert.

Related area	Symptoms	
Skin	Rash · Redness, itching	
Digestive organ	Nausea · vomiting, loss of appetite	
Cental nervous system	Dizzy	
Respiratory organ	Shortness, Stuffy of breath	
Urology	Dysuria	
Others	Excessive hypothermia	

In very rare cases, the following serious symptoms may occur. In this case, please get medical attention immediately.

Related area	Symptoms	
Shock(Anaphylaxis)	Immediately after taking medication, itching of the skin, urticarial, hoarseness of voice, sneezing, throat itching, breathing, palpitations, turbulence of consciousness etc. appears.	
Skin mucosal eye syndrome (Stevens-Johnson syndrome), Toxic epidermal necrolysis, Acute pestiated pustule.	High fever, Redness of the eyes, Rashes, Sores on the lips, Sores in the throat, Extensive rasheredness on the skin, Small bumps (small blisters) on reddened skin. Heavy of Whole body. Persistent loss of appetite or Rapid worsening of symptoms.	
Liver dysfunction	It shows fever, itching, rash, jaundice (yellowing of the skin and whites of the eyes), brown urine, whole body dullness, loss of appetite, etc. appear.	
Renal disorder	Fever, rash, decreased urine output volume, general whole body swelling or sagging, joint pain (nodal pain), diarrhea, etc. may appear.	
Interstitial pneumonia	If you go up the stairs or you will run out of breath. And you may feel stuffy, empty cough, fever, etc. These will be suddenly appear or persist.	
Asthma	When you breathe, the bronchus will squeeze with wheezing, whistling and a feeling of stuffiness appears.	

Aplastic anemia	Bruising, nosebleeds, gum bleeding, fever, skin and mucous membranes appear pale, fatigue, palpitations, shortness of breath, mood worsening, bloodsheds etc. appear.
Agranulocytosis	Sudden high fever, chills, sore throat etc. appear.

3 The following symptoms may appear after taking this medicine, so if such symptoms persist or increase. Please stop taking it and consult a doctor, pharmacist or registered distributor with the Japanese package insert.

Mouth thirst or Sleepiness.

4 If these symptoms do not improve after having used this medicine 5 or 6 days, stop taking the medicine, and consult a doctor, pharmacist, or registered distributor with the Japanese package insert.

Directions

Please take the following amount with the attached scale with measuring cup, 3 times a day after meals and before occupation if necessary. In some cases, you can take up to 6 times a day at an interval of about 4 hours.

Age	One dose	Number of doses per day
3∼7 years old	10mL	3 to 6 times
1∼3 years old	7mL	
6 months more ~ under 1 year old	6mL	
3 ∼6 months	5mL	
Less than 3 months		Do not use

[When using this product]

- (1) Please follow the recommended dosage and directions.
- (2) This medicine should be given to children only under adult supervision.
- (3) To use for infants younger than 2 years, please priority to letting the doctor' consult, and so you will give this medicine only when you are unavoidable case.

Other information

(1) Store in a cool and dry with less humidity place free from direct sunlight by a seal tightly.

- (2) Keep all medicine out of the reach of children.
- (3) Do not transfer this medicine to a different container. (In this case, cause misuse or change quality)
- (4) Please wipe the mouth of the bottle after taking it, tighten the lid. If it is too bad, internal fluid may flow out or contaminate.
- (5) Please wash the measuring cup well after taking this medicine and keep it clean.
- (6) After opening once, please use up as early as possible from the point of quality preservation.
- (7) Please do not take medicines that have passed the expiration date

[Request for storage]

When the cap is tight, warm the cap with hot water $(50-60\,^\circ$ C), taking care not to enter hot water into the bottle. In that case, if the temperature of the hot water is too high, please be careful not to get burnedand and not to cause injury by broken the bottle.

Inactive ingredients:

Sugar, D – sorbitol, Na Benzoate, Paraben, Ethanol, Polyoxyethylene hardened castor oil, Caramel, Perfume, Glycerin, Vanillin, Propylene glycol.

Questions or comments?

If you have any suggestions about this product, please contact the shop you purchased or the following address.

Reception time 9:00~12:00·13:00~17:00 (Excluding weekends and holidays)

[Request of limited correspondence]

<Kyowa-Gifu-Japan>

- (1) In case of telephone consultation, please only in Japanese for a while.
- (2) The latest Japanese package insert is available on the website of Kyowa Pharmaceutical Co., Ltd. (www.kyowa-ci.co.jp).

Disclaimer statement

(1) We use a format similar to the FDA OTC Drug Regulations, but this is not an OTC Drug approved under the FDA. Please note that it is licensed for domestic use in accordance with the Pharmaceutical Affairs Law of Japan..

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