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Designated 2nd Class OTC drug

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

コルゲンコーワ総合かぜ薬

COLGEN KOWA COLD MEDICINE

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) Have had asthma after using this medicine, other cold medicines or antipyretic analgesics.

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

Other cold medicines, antipyretic analgesics, sedatives, antitussives and expectorants, oral medicines, etc. containing antihistamine (Oral medicines for rhinitis, motion sickness medicines, and allergy medicines, etc.)

3. Do not drive or operate machinery after use. (Sleepiness, etc. may occur.)

4. Do not drink alcohol before and after use.

5. Do not use over a long period consecutively.

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 or dentist.
- (2) Are pregnant or may possibly be pregnant.
- (3) Are breastfeeding.
- (4) Are elderly.
- (5) Have ever had allergic reaction to any medicines, etc.
- (6) Have the following symptoms: High fever, dysuria
- (7) Have been diagnosed with the following conditions: Thyroid dysfunction, diabetes, cardiac disease, hypertension, liver disease, kidney disease, gastric/duodenal ulcer, glaucoma, thrombosis (cerebral thrombosis, myocardial infarction, thrombophlebitis), at risk of having thrombosis

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, loss of appetite
Psychoneurotic system	Dizziness
Respiratory organs	Shortness of breath, difficulty in breathing
Urinary organs	Dysuria
Others	Excessive decrease in body temperature

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.
Oculo-muco-cutaneous syndrome (Stevens-Johnson syndrome), toxic epidermal necrolysis, acute generalised exanthematous pustulosis	Symptoms such as high fever, ocular hyperemia, eye discharge, lip erosion, sore throat, widespread rash/redness of the skin, small pimples (small pustules) on reddened skin, general malaise, anorexia etc. may persist or worsen suddenly.
Drug-induced hypersensitivity syndrome	Widespread skin redness, generalized rash, fever, general malaise, swelling of lymph nodes (neck, armpits, groin, etc.), etc. are developed.
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.

(Continued overleaf)

Kidney disorders	Symptoms such as fever, rash, decrease in urinary output, generalized swelling, general malaise, arthritic pain (joint pain), diarrhea, etc. may occur.
Interstitial pneumonia	Symptoms such as shortness of breath/difficulty in breathing from climbing stairs or other hard activities, dry cough, fever, etc. may suddenly occur or persist.
Asthma	Symptoms such as wheezing, whistling or difficulty in breathing, etc. may occur.
Aplastic anemia	Symptoms, such as bruises, nose bleeds, bleeding gums, fever, pale appearance of skin and mucosa, fatigue, palpitations, shortness of breath, becoming dizzy from feeling sick and blood in the urine, etc. may occur.
Agranulocytosis	Symptoms, such as acute high fever, chills and sore throat, etc. 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

4. If symptoms do not improve after using 5 or 6 times, stop use and ask a doctor, pharmacist or registered salesperson with the package insert.

Indications

Relief of cold symptoms (sore throat, runny nose, nasal congestion, sneezing, cough, sputum, fever, chills due to fever, headache, joint pain, muscle pain)

Dosage/directions

Please take the following dosage with water or warm water within 30 minutes after a meal without chewing.

Age	One dose	Daily dose
Adults (15 years and older)	3 tablets ○○○	3 times
11-14 years of age	2 tablets ○○	
5-10 years of age	1 tablet ○	
Children (Under 5 years of age)	✗ Do not use.	

<Precautions for dosage/directions>

(1) Follow the dosage/directions.

(2) This medicine should be given to children only under supervision of their guardians.

Ingredients/contents (in 9 tablets)

- Acetaminophen 900mg ● Tranexamic acid 420mg ● d-chlorpheniramine maleate 3.5mg
- Dextromethorphan hydrobromide hydrate 48mg ● dl-methylephedrine hydrochloride 60mg
- Anhydrous caffeine 75mg ● Hesperidin 60mg

[Inactive ingredients] Hydroxypropyl cellulose, carmellose calcium, cellulose, magnesium stearate

<Precautions for ingredients/contents>

Spots may appear on the surface of the tablet due to the hesperidin contained in the drug.



Precautions for storage and handling

(1) Store in a cool and dry place avoiding high temperatures, humidity, and direct sunlight, with cap tightly closed.

(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) When tablets get wet with water, the surface of tablets may be discolored or cracked. Therefore, avoid falling water drops on tablets or handling tablets with wet hands. If tablets accidentally become wet, discard the wet tablets.

(5) The cushioning material in the bottle is for protection of tablets during transportation. Make sure to discard the material once the cap is opened.

(6) If the cap of the bottle is not closed tightly, the quality may deteriorate due to moisture in the air. Therefore, close the cap tightly after each use.

(7) Do not use this product after its validity date (printed on the outer box and on the label) has expired.

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