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[*: October, 2024 Revision of underlined parts]

Pharmaceuticals requiring guidance

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

Cold medicine **コルゲンコーワLX錠**
COLGEN KOWA LX TABLET

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.
- (3) Are children under 15 years of age.
- (4) Are currently treated at a medical care provider. Gastric/duodenal ulcer, liver disease, kidney disease, cardiac disease
- (5) Have been identified by a doctor that you had a hematological abnormality (blood disease) such as a low red blood cell count (anemia), a low blood platelet count (prolonged bleeding, easy bleeding), a low leukocyte count, etc.
- (6) Are women within the last 12 weeks of pregnancy.

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 use during breastfeeding; avoid breastfeeding when using this medicine.

5. Do not drink alcohol before and after use.

6. Do not use for more than 5 days.

What to ask a doctor or pharmacist

1. Ask a doctor or pharmacist before use if you:

- (1) Are currently treated by a doctor or dentist.
- (2) Are pregnant or may possibly be pregnant.
- (3) Are elderly.
- (4) Have ever had allergic reaction to any medicines, etc.
- (5) Have the following symptoms: High fever, dysuria
- (6) Have been diagnosed with the following conditions: Bronchial asthma, ulcerative colitis, Crohn's disease, systemic lupus erythematosus, mixed connective tissue disease, thyroid dysfunction, diabetes, heart disease, hypertension, glaucoma, respiratory dysfunction, obstructive sleep apnea syndrome, obesity
- (7) Have had the following diseases: Gastric/duodenal ulcer, liver disease, kidney disease, blood disease

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 or pharmacist with the package insert.

(1) Symptoms such as excessive decrease in body temperature, prostration (feel weak), cold extremities (feel cold in your limbs), etc. may occur. (2) Peptic ulcer and swelling may occur. Furthermore, serious symptoms such as gastrointestinal hemorrhage (vomiting blood, nausea/vomiting, abdominal pain, black tarry stool, or bloody stool, etc. may occur), gastrointestinal perforation (it means perforation of the alimentary tract. Symptoms such as nausea/vomiting, intense abdominal pain, etc. may occur), stenosis and obstruction of small/large intestines (nausea/vomiting, abdominal pain and abdominal bloating, etc. may occur) may rarely occur. In such cases, ask a doctor and receive medical treatment immediately. (3) The following symptoms may occur.

Related area	Symptom
Skin	Rash/redness, itching
Digestive organs	Nausea/vomiting, loss of appetite, heartburn, abdominal pain, stomatitis, stomach distress, feeling of fullness in the abdomen, indigestion
Psychoneurotic system	Dizziness, headache, numbness, sleepiness
Circulatory organs	Palpitation, blood pressure increased
Urinary organs	Haematuria
Others	Fever, facial flushing, anaemia, malaise, chest pain

The following serious symptoms may rarely occur. In such cases, ask a doctor and receive medical treatment immediately.

(Continued overleaf)

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, erythema multiforme, acute generalised exanthematous pustulosis	Symptoms such as high fever, ocular hyperemia, eye discharge, lip erosion, sore throat, widespread rash/redness of the skin, blisters on the red part of the skin, small pimples (small pustules) on reddened skin, general malaise, anorexia etc. may persist or worsen suddenly.
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.
Kidney disorders	Symptoms such as fever, rash, decrease in urinary output, generalized swelling, general malaise, arthritic pain (joint pain), diarrhea, etc. may occur.
Aseptic meningitis	Intense headache with stiffness in neck, fever, nausea/vomiting, etc. may occur. (These symptoms have been reported frequently particularly in people receiving treatments for systemic lupus erythematosus or mixed connective tissue disease.)
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.
Rhabdomyolysis	Feel pain in muscles of limbs, shoulders and low back, etc., numbness of the limbs, feel weak, feel body tense, general malaise, reddish brown urine, etc. occur.
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.
Blood disorders	Sore throat, fever, general malaise, face or the back side of eyelid are whitened, blood easily (bleeding gums, nosebleed, etc.) or bruising (color does not disappear even when pushing), etc. may occur.
Congestive heart failure	General malaise, palpitation, shortness of breath, chest distress, chest pain, dizziness, fainting, etc. may occur.
Myocardial infarction*	Constricting chest pain, shortness of breath, and cold sweat.*
Cerebrovascular disease*	Symptoms include sudden decrease or loss of consciousness, difficulty moving one side of the body, headache, vomiting, dizziness, difficulty speaking, or speech troubles.*
Respiratory depression	Symptoms such as shortness of breath, difficulty in breathing, etc. may occur.

3. The following symptoms may occur after use; in case these symptoms persist or worsen, stop use and ask a doctor or pharmacist with the package insert.

Dry mouth, constipation, diarrhea, sleepiness

4. If symptoms do not improve after using 5 or 6 times (particularly if fever persists for 3 days or longer, or comes back repeatedly), stop use and ask a doctor or pharmacist with the package insert.

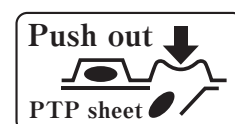
Indications

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

Dosage/directions

Take the tablets with room temperature or warm water within 30 minutes of each meal as much as possible.

Age	One dose	Daily dose
Adults (15 years and older)	3 tablets ○○○	3 times
Children (Under 15 years of age)	✗ Do not use.	



<Precautions for dosage/directions>

(1) Follow the dosage/directions.

(2) How to take out tablets: As shown on the above illustration, strongly press the convex part of the PTP sheet with your finger tip to break the aluminum foil on the back and take out a tablet. (Accidental swallowing the PTP sheet may cause an unexpected accident, such as esophageal mucosa penetration, etc.)

Ingredients/contents (in 9 tablets)

●Loxoprofen sodium hydrate 204.3mg (180mg as anhydrate) ●Dihydrocodeine phosphate 24mg ●d-Chlorpheniramine maleate 3.5mg ●dl-Methylephedrine hydrochloride 60mg ●Guaifenesin 250mg ●Anhydrous caffeine 40mg

[Inactive ingredients] Cellulose, hydroxypropyl cellulose, carmellose calcium, anhydrous dibasic calcium phosphate, magnesium aluminometasilicate, magnesium stearate, hypromellose, macrogol, talc, titanium oxide, iron sesquioxide, carnauba wax

Precautions for storage and handling

- (1) Store in a cool and dry place avoiding high temperatures, humidity, and direct sunlight.
- (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) Store and handle this product carefully so as not to break the aluminum foil of the PTP sheet or to damage the tablets inside.
- (5) Do not use this product after its validity date has expired (printed on the outer box).

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Y1791R S4K A1