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[* : July, 2017 Revision of underlined parts]

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

Designated 2nd Class OTC drug

Cold medicine **コルゲン^{ユーワ}IB錠TX**
COLGEN KOWA IB TABLET TX

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 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.), oral medicines containing tranexamic acid

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, 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 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: Thyroid dysfunction, diabetes, cardiac disease, hypertension, liver disease, kidney disease, glaucoma, systemic lupus erythematosus, mixed connective tissue disease, thrombosis (cerebral thrombosis, myocardial infarction, thrombophlebitis) and at risk of having thrombosis, respiratory dysfunction, obstructive sleep apnea syndrome, obesity*
- (7) Have had the following diseases: Gastric/duodenal ulcer, ulcerative colitis, Crohn's 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, pharmacist or registered salesperson with the package insert.

Related area	Symptom
Skin	Rash/redness, itching, bruising
Digestive organs	Nausea/vomiting, loss of appetite, stomach distress, stomachache, stomatitis, heartburn, heavy feeling in the stomach, gastrointestinal bleeding, abdominal pain, diarrhea, bloody stool
Psychoneurotic system	Dizziness
Circulatory organs	Palpitation
Respiratory organs	Shortness of breath
Urinary organs	Dysuria
Others	Blurred vision, ringing in ears, swelling, nosebleed, bleeding gums, prolonged bleeding, bleeding, back pain, excessive decrease in body temperature, malaise

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.

(Continued overleaf)

Oculo-muco-cutaneous syndrome (Stevens-Johnson syndrome), toxic epidermal necrolysis	Symptoms such as high fever, ocular hyperemia, eye discharge, lip erosion, sore throat, widespread rash/redness of the skin, 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.
Asthma	Symptoms such as wheezing, whistling or difficulty in breathing, etc. may occur.
Aplastic anemia	Symptoms such as bruising, nosebleed, bleeding gums, fever, pale skin and mucosa, feeling of fatigue, palpitation, shortness of breath, feeling of sickness and dizziness, hematuria, etc. may occur.
Agranulocytosis	Sudden high fever, chills, sore throat, etc. may occur.
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, pharmacist or registered salesperson with the package insert.

Constipation, dry mouth, 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, pharmacist or registered salesperson with the package insert.

Indications

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

Dosage/directions

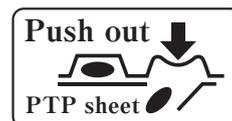
Take the tablets with room temperature or warm water within 30 minutes of each meal as much as possible.

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, 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)

●Ibuprofen 450mg ●Tranexamic acid 750mg ●d-chlorpheniramine maleate 3.5mg ●Dihydrocodeine phosphate 24mg
●dl-methylephedrine hydrochloride 60mg ●Guaifenesin 250mg ●Anhydrous caffeine 75mg

[Inactive ingredients] Citric acid, carmellose calcium, lactose, silicic anhydride, calcium silicate, magnesium stearate, hypromellose, triacetin, titanium oxide, Yellow No. 5, 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).

Marketing Authorization Holder Kowa Company, Ltd. 3-4-14, Nihonbashi-Honcho, Chuo-ku, Tokyo