PANCOLD S - guaifenesin liquid
Kafus Co., Ltd

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Guaifenesin
Caffeine anhydrous
Chlorpheniramine maleate
dl-methylephedrine hydrochloride
Acetaminophen

alcohol, citric acid, edentate sodium, high fructose corn syrup, lemon essence, methylparaben, monosodium glutamate, orange essence, propylene glycol, propylparaben, sodium benzoate, sodium chloride, water, tartrazine

Temporarily relieves these minor symptoms due to a cold or the flu:
▪aches ▪pain ▪headache ▪sore throat ▪muscular aches ▪fever
▪rummy nose ▪sneezing ▪itching of the nose and throat
▪nasal congestion ▪sinus congestion and pressure
▪cough due to minor throat and bronchial irritation

keep out or reach of the children

Adults and children 12 years and older: Take 1 bottle every 4 hours, while symptoms persist not to exceed 6 bottles in 24 hours, or as directed by a doctor.

Alcohol warning:
▪If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. ▪Acetaminophen may cause liver damage.

for oral use only

Composition : Each bottle (30mL)
Guaifenesin(KP) - 83.3mg, Caffeine (KP) - 30mg,
Chlorpheniramine maleate (KP) - 2.5mg,
dl-Methylephedrine HCl (KP) - 17.5mg, Acetaminophen (KP) - 300mg,
Propyl parahydroxybenzoate (KP) - 1.8mg,
Methyl parahydroxybenzoate - 3.6mg, Sodium benzoate (KP) - 28.5mg,
Aspartame (KFA) - 22.5mg, KFDA approved Tar colorant (Yellow No.4 , Yellow No.5)
Description : Yellow transparent solution
Indication : Symptomatic relief of the common cold (runny nose, stuffy nose, sneezing, cough, sore throat, sputum, chill, fever, headache, joint pain, myalgia)
Dosage and Administration : Adult, 30mL, 3 times daily, 30minutes after meals
Precautions
1. Warning
1) Person who takes more than 3 cups of alcohol everyday should consult physician or pharmacist before using this medicine or another antipyretic analgesics. If that person take this medicine, liver damage may be induced. 2) Aspartame that is included in this medicine is decomposed and metabolized into phenylalanine in a body. Therefore this medicine should not be used to patients with the genetic condition phenylketonuria, who need limited phenylalanine intake.
2. Contraindication
1) Patients with a history of hypersensitivity to this medicine (for example, rash, flare, itch, edema (larynx, eyelid, lip). ▶

2) Patients who experienced asthma with this drug, other cold remedy or antipyretic analgesics.
3. Following patients should be administered this medicine with care.
This medicine contains Yellow No.4 (Tartrazine). Therefore, It should be carefully administered to patients who have a hypersensitivity or allergy to the component.
4. Following patients should consult physician or pharmacist before using.1) Patients with familial aggregation of allergic reaction including urticaria, contact dermatitis, allergic rhinitis, migraine and food allergy. 2) Patients who have diseases such as hepatic, renal or thyroid disorder, diabetes, hypertension, fragile person, person with high fever. 3) Patients who have cardiac disorder or elderly person. 4) Pregnant women or women of childbearing potential, nursing mothers.
5. Cautions on administration
1) This medicine should not be concurrently used with other antitussive expectorant, cold remedy, antihistamine and sedative
2) It is not recommended to engage in hazardous activities such as operating machinery or driving a motor vehicle during therapy.
3) Following symptoms were rarely reported with this medicine. In the event of the following symptoms, therapy should be immediately discontinued and patients consult physician or pharmacist.
①In case that urticaria, edema (larynx, eyelid, lip etc),pale face with heart oppressing sense, cooling in hands and feet, cold sweating and gasping occur just after this medicine is taken. ②The case that violent symptoms such as rash, flare and Burning-form bleb are appeared in a mouth. ▶

general body and eye mucous membrane with high fever. ③In the onset of asthma
4) In the patients who received barbiturates, tricycle antidepressant or alcohol sedatives, ability to metabolize acetaminophen is decreased, and results increase of the half life of serum acetaminophen. Alcohol may increase hepatotoxicity of acetaminophen overdose.
6. General caution : This medicine contains sodium benzoate, which may cause slight irritation on skin, eye and mucous membrane .
7. Adverse reactions : exanthema, flare, nausea, vomiting, constipation, anorexia, dysuria or vertigo
8. Others : Keep out of reach of children. Protect from direct sunlight and store in a dry and cool place.
9. Daily Limit of Aspartame : It is controlled below WHO recommended daily dose of Aspartame (40mg/kg/day) . 60kg Adult : Maximum daily dose : 2.4g
Store below : 1 ~ 30℃
Manufactured by :
DONG WHA PHARM. CO., LTD. Seoul, Korea
504-3, Yongtan-dong, Chungju-city, Chungcheongbuk-do, Korea.
Distributed by :

MADE IN KOREA

DONGWHA PHARM

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DONGWHA PHARM

PANCOLD S 판콜에스

30ml×30

DONGWHA PHARM

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PANCOLD S

판콜에스

Symptomatic relief of the common cold

PANCOLD S

DONGWHA PHARM

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PANCOLD S

PANCOLD S

guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55277-1001
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	83.3 mg in 30 mL
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	30 mg in 30 mL
CHLORPHENIRAMINE (UNII: 3U6IO1965U) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE	2.5 mg in 30 mL
METHYLEPHEDRINE HYDROCHLORIDE, DL- (UNII: 99214P83XM) (METHYLEPHEDRINE, DL- - UNII:SHS9PGQ2LS)	METHYLEPHEDRINE HYDROCHLORIDE, DL-	17.5 mg in 30 mL
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	300 mg in 30 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
LEMON (UNII: 24RS0A988O)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MONOSODIUM GLUTAMATE (UNII: W81N5U6R6U)	
ORANGE (UNII: 5EVU04N5QU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55277-1001-1	30 mL in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/15/2013	

Labeler - Kafus Co., Ltd (688445679)

Registrant - Kafus Co., Ltd (688445679)

Establishment

Name	Address	ID/FEI	Business Operations
Dong Hwa Pharm Co., Ltd		687745240	manufacture(55277-1001)

Revised: 1/2013 Kafus Co., Ltd