PANCOLD A- acetaminophen, guaifenesin, pentoxyverine citrate, phenylpehrine hydcrochloride, chlorpheniramine maleate, caffeine anhydrous liquid
DONGWHA PHARM. CO. LTD.

PANCOLD A ORAL SOLUTION

ACTIVE INGREDIENTS

Active ingredients (in each 30 mL bottle)

- Acetaminophen 300 mg
- Guaifenesin 80 mg
- Pentoxyverine citrate 15 mg
- Phenylephrine Hydrochloride 10 mg
- Chlorpheniramine maleate 2.5 mg
- Caffeine 30 mg

PURPOSE

Pain Reliever-Fever Reducer, Expectorant, Antitussive, Nasal Decongestant, Antihistamine, Pain reliever aid

INDICATIONS & USAGE

Uses temporarily relieves these common cold symptoms:

- runny nose & sneezing
- nasal congestion
- sore throat
- cough
- phlegm
- chills
- fever
- headache
- joint pain
- muscle pain

WARNINGS SECTION

Warnings

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more glasses of alcohol everyday while using this product

Allergy alert: acetaminophen mat cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

- **Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

DO NOT USE

Do not use

- if you ever had an allergic reaction to this product or any of its ingredients
- with any other drug containing acetaminophen. If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- If you are taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson’s disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains MAOI, ask a doctor or pharmacist before taking this product.
- If you are taking expectorants, other cold drugs, antipyretic-analgesics, sedatives, oral drugs containing antihistamines (oral drugs for rhinitis, motion sickness drugs, and allergy drugs)

ASK A DOCTOR

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to enlarge prostate gland
- persistent or chronic cough such as occurs with smoking, asthma or emphysema
- cough that occurs with too much phlegm (mucus)
- glaucoma (eye pain, blurred vision)
- weak body
- high fever

STOP USE

Stop use and ask doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion or cough gets worse or last more than 7 days
- fever gets worse or lasts more than 3 days n redness or swelling is present
- cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition.

PREGNANCY OR BREAST FEEDING

If pregnant or breast-feeding, ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

OVERDOSAGE

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptom.

DOSAGE & ADMINISTRATION

Directions

- do not take more than directed (see overdose warning)

Adults:	Take 1 bottle (30mL) three times a day, 30 minutes after meal.
Children and infants:	Do not administer. Ask a doctor.

STORAGE AND HANDLING

Other nformation

- store at room temperature between 15°-25°C (59°-77°F) and avoid direct sunlight

INACTIVE INGREDIENTS

- **Inactive Ingredients:** : alcohol, citric acid monohydrate, edetate disodium, fructooligosaccharide, lemon flavor, orange flavor, propylene glycol, sodium citrate, sucralose, water

PANCOLD A

acetaminophen, guaifenesin, pentoxyverine citrate, phenylpehrine hydcrochloride, chlorpheniramine maleate, caffeine anhydrous liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51352-189
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	80 mg in 30 mL
PENTOXYVERINE CITRATE (UNII: 4SH0MFJ5HJ) (PENTOXYVERINE - UNII:32C726X12W)	PENTOXYVERINE CITRATE	15 mg in 30 mL
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	300 mg in 30 mL
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2.5 mg in 30 mL
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	30 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CITRATE (UNII: 1Q73Q2JULR)	32.4 mg in 30 mL
SUCRALOSE (UNII: 96K6UQ3ZD4)	10 mg in 30 mL

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	29 mg in 30 mL
EDETATE DISODIUM (UNII: 7FLD91C86K)	3 mg in 30 mL
ALCOHOL (UNII: 3K9958V90M)	0.5 mL in 30 mL
SACCHARUM OFFICINARUM STEM FRUCTOOLIGOSACCHARIDES (UNII: 8LLD82AE3S)	7.5 g in 30 mL
WATER (UNII: 059QF0KO0R)	
ORANGE (UNII: 5EVU04N5QU)	
LEMON (UNII: 24RS0A988O)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	ORANGE (Light yellowish clear oral liquid with orange-lemon flavor.)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51352-189-73	3 in 1 CASE	07/01/2023	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:51352-189-75	5 in 1 CASE	12/07/2023	
2		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/01/2023	

Labeler - DONGWHA PHARM. CO. LTD. (687745240)

Registrant - DONGWHA PHARM. CO. LTD. (687745240)

Establishment

Name	Address	ID/FEI	Business Operations
DONGWHA PHARM. CO., LTD.		687745240	manufacture(51352-189)

Revised: 12/2023 DONGWHA PHARM. CO. LTD.