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

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### 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, guaifenes in, 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	<b>Basis of Strength</b>	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: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	300 mg in 30 mL	
CHLORPHENIRAMINE MALEATE (UNII: V1Q0090J9Z) (CHLORPHENIRAMINE - UNII:3U6I01965U)	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: 1WS 297W6MV)	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)	
<b>LEMON</b> (UNII: 24RS0A9880)	

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

P	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	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	<b>Business Operations</b>		
DONGWHA PHARM. CO., LTD.		687745240	manufacture(51352-189)		

Revised: 12/2024 DONGWHA PHARM. CO. LTD.