

**COLDTAC PLUS- acetaminophen, phenylephrin hydrochloride,
dextromethorphan hydrobromide tablet
OPMX LLC**

COLDTAC Plus

Drug Facts

Active Ingredients (in each tablet)

Acetaminophen USP 325mg.....	Pain reliever/fever reducer
Guaifenesin USP 200mg.....	Expectorant
Phenylephrine HCL USP 5mg.....	Decongestant
Dextromethorphan HBr USP 15mg.....	Antitussive

Purpose

Pain reliever/ fever reducer
Expectorant
Decongestant
Antitussive

Uses

Temporarily

- Relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- Relieves sinus congestion and pressure, helps decongest sinus openings and passages
- Restores freer breathing
- Helps loosen bothersome mucus, drain bronchial tubes, and make coughs more productive
- Suppresses cough due to minor throat and bronchial irritation associated with a cold or inhaled irritants
- Temporarily relieves minor aches, pains and fever associated with: headache, common cold, toothache, backache, muscular aches, menstrual cramps

Warnings:

Liver Warning:

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

- More than 8 tablets in 24 hours
- With other drugs containing acetaminophen (prescription or nonprescription). Ask a doctor or pharmacist before using with other drugs if you are not sure
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may 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

- with any other product containing **acetaminophen** (prescription or nonprescription).

If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

- if you are now 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 MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- for more than 7 days for pain and 3 days for fever, unless directed by a doctor

Ask a doctor before use

if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to enlarged prostate gland
- a cough that is accompanied by excessive phlegm (mucus)
- a persistent or chronic cough such as occurs with smoking, asthma or emphysema

Ask a doctor or pharmacist

before use if you are

- taking the blood thinning drug warfarin

Stop use and ask a doctor if

- new symptoms occur
- redness or swelling is present
- pain or fever persists or gets worse
- nervousness, dizziness, or sleeplessness occur
- a persistent cough or symptoms do not improve within 7 days, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

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

Directions:

- **do not exceed recommended dosage**
- **adults and children 12 years of age and over:**

take 2 tablets every 6 - 8 hours; **do not exceed 8 tablets** in a 24-hour period

- **children under 12 years of age:** consult a doctor

Other Information

- store at room temperature 59° to 86°F (15° to 30°C)
- Avoid excessive heat and humidity

TAMPER EVIDENCE: Do not use if packet is open or torn.

Inactive Ingredients

Corn starch, crospovidone, microcrystalline cellulose, povidone k30, silicon dioxide, stearic acid, talc, water

Questions & comments?

Call: 619-600-5632 (Mon-Fri 9am - 5pm EST)

NDC 69729-143-06

COLDTAC Plus

Tablets

Acetaminophen 325 mg / Guaifenesin 200 mg

Dextromethorphan HBr 15 mg / Phenylephrine HCl 5 mg

NDC 69729-143-02 

COLDTAC

Plus

2 Tablets

ACTIVE INGREDIENTS (in each tablet)	PURPOSE
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 15 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal Decongestant

Effective and quick relief from
cold, cough & flu symptoms
Eficaz y rápido alivio de los síntomas del
resfriado, tos y gripe

- ◆ Pain reliever / fever reducer / Fiebre y cuerpo cortado
- ◆ Cough Suppressant / Supresor de la tos
- ◆ Expectorant / Expectorante
- ◆ Nasal Decongestant / Descongestivo nasal

READ AND KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Uses ■ temporarily relieves common cold/flu symptoms: ■ nasal decongestion ■ sinus congestion & pressure ■ cough due to minor throat & bronchial irritation ■ minor aches & pains ■ headache ■ fever ■ sore throat ■ reduces swelling of nasal passages ■ temporarily restores freer breathing through the nose ■ promotes nasal and/or sinus drainage ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

Warnings: Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take: ■ more than 8 tablets in 24 hrs, which is the maximum daily amount for this product ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may 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.

Other information ■ Store at room temperature 25°C (77°F); excursions permitted between 15°C - 30°C (59°F - 86°F)

■ Avoid excessive heat and humidity

REV. 01.2024



A36BA01-01

Exclusively distributed by:



Made for:



TAMPER EVIDENT: DO NOT USE IF POUCH IS TORN, BROKEN OR SHOWS ANY SIGN OF TAMPERING

COLDTAC PLUS

acetaminophen, phenylephrin hydrochloride, dextromethorphan hydrobromide tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-143
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POVIDONE K30 (UNII: U725QWY32X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSPVIDONE (UNII: 2S7830E561)	
TALC (UNII: 7SEV7J4R1U)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	Score	2 pieces
Shape	CAPSULE	Size	16mm
Flavor		Imprint Code	A15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-143-06	6 in 1 PACKAGE	01/05/2018	
1	NDC:69729-143-02	2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:69729-143-72	72 in 1 PACKAGE	01/05/2018	
2	NDC:69729-143-02	2 in 1 POUCH; 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	01/05/2018	

Labeler - OPMX LLC (029918743)

Revised: 2/2024

OPMX LLC