

COLDTAC PLUS SOFTGELS- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled OPMX LLC.

Coldtac Plus - Softgels

Drug Facts

<i>Active ingredients (in each Softgel)</i>	<i>Purpose</i>
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

Temporarily relieves common cold/flu symptoms:

- Nasal congestion
- Cough due to minor throat & bronchial irritation
- Sore throat
- Headache
- Minor aches & pains
- Fever

Warnings

Liver warning

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

- more than 4 doses in 24 hrs, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily 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, lasts 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 drug 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 the MAOI drug.
- If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- Liver disease
- Heart disease
- Diabetes
- High blood pressure
- Trouble urinating due to enlarged prostate gland
- Cough that occurs with too much phlegm (mucus)
- Persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis or emphysema.

Ask a doctor or pharmacist before use if you are: Taking the blood thinning drug warfarin.

When using this product,

do not use more than directed.

Stop use and ask a doctor if

- You get nervous, dizzy or sleepless.
- Symptoms get worse or last more than 5 days (children) or 7 days (adults).
- Fever gets worse or lasts more than 3 days.
- Redness or swelling is present.
- New symptoms occur.
- Cough comes back, or occurs with rash or headache that lasts. These could be signs of a serious condition.

Keep out of reach of children.

If pregnant or breast-feeding,

ask a health professional before use.

Overdose warning

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well for children even if you do not notice any signs or symptoms.

Directions

- Take only as directed.
- Do not exceed 4 doses per 24 hrs.

Adults & children 12 yrs & over	2 softgels with water every 4 hrs
Children 4 to under 12 yrs	Ask a doctor
Children under 4 yrs	Do not use

Other information

- Store at room temperature.

Inactive ingredients

FD&C Red No. 40, FD&C Yellow No. 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special, titanium dioxide.

Questions?

Call to free 619-600-5632 Monday through Friday 9AM - 5PM EST

Made for:

RRX

Exclusively distributed by:

OPMX

Chula Vista, CA 91910

Phone: 619-600-5632

PRINCIPAL DISPLAY PANEL

NDC 69729-120-10

Coldtac Plus

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5mg

Pain reliever, fever reducer/ Fiebre y cuerpo cortado

Nasal Decongestant/ Descongestivo nasal

Cough Suppressant/ Supresor de la tos

Contents/Content

10 Softgels/ Capsulas de Gel

Drug Facts (continued)

Active ingredients (in each softgel)
 Acetaminophen 325 mg, Pain reliever/fever reducer
 Dextromethorphan HBr 10 mg, Cough suppressant
 Phenylephrine HCl 5 mg, Nasal decongestant

Purposes
 Relieves pain, reduces fever, suppresses cough, and relieves nasal congestion.

Warnings
 • Severe liver damage may occur if you take more than 4 doses in 24 hrs, which is the maximum daily amount for this product. • With other drugs containing acetaminophen. • 3 or more alcoholic drinks daily while using this product.

Uses
 Temporarily relieves common cold/flu symptoms. • Nasal congestion • Cough due to minor throat & bronchial irritation • Sore throat • Headache • Minor aches and pains • Fever

Directions
 • Adults & children 12 yrs & over: 2 softgels with water every 4 hrs. Do not exceed 4 doses per 24 hours. • Take only as directed.

Other information
 • Store at room temperature.

Inactive ingredients: FD&C Red No. 40, glycol, polyethylene glycol, purified water, sorbitol, titanium dioxide.

Questions?
 Call toll free 619-600-5632 Monday through Friday 9AM - 5PM EST

Rev. 04.2023 Item # RRX1121
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TAMPER EVIDENT:
 Do not use if package is opened or if blister unit is torn, broken or shows any sign of tampering.



Exclusively distributed by:
OPMX
 Chula Vista, CA 91910
 Phone: 619-600-5632

Made for:
RRX
 San Diego, CA

COLDTAC Plus
 Softgels / Cápsulas de Gel

COLDTAC Plus

Acetaminophen 325mg
 Dextromethorphan HBr 10 mg
 Phenylephrine HCl 5mg

Effective and quick relief from cough, cold & flu symptoms

Eficaz y rápido alivio de los síntomas del resfriado, tos y gripe

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

10 Contents / Contenido Softgels / Cápsulas de Gel




COLDTAC Plus
 Softgels / Cápsulas de Gel

RRX

Lot No.:
 Exp. date

READ & KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

COLDTAC PLUS SOFTGELS
 acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid

filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-120
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	AP01
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-120-10	1 in 1 CARTON	06/30/2023	
1		10 in 1 BLISTER PACK; 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	06/30/2023	
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Labeler - OPMX LLC. (029918743)

Revised: 4/2024

OPMX LLC.