

**COLDTAC ULTRA- acetaminophen 325mg, chlorpheniramine maleate 2mg, phenylephrine hcl
5mg tablet
OPMX LLC**

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.

COLDTAC ULTRA

DRUG FACTS

ACTIVE INGREDIENTS:

Acetaminophen USP 325mg.....Pain reliever
Chlorpheniramine Maleate USP 2mg.....Antihistamine
Phenylephrine HCL USP 5mg.....Nasal decongestant

Purpose

Pain reliever
Antihistamine
Nasal decongestant

USES

Temporarily relieves these symptoms of hay fever or other upper respiratory allergies:

- headache
- sinus congestion and pressure
- nasal congestion
- runny nose and sneezing
- minor aches and pains

Temporarily relieves these additional symptoms of hay fever:

- itching of the nose or throat
- itchy, watery eyes
- helps clear nasal passages
- helps decongest sinus openings and passages

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 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

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 a MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients
- to make a child sleepy

Ask a doctor before use if you have

liver disease, heart disease, high blood pressure, thyroid disease, diabetes, trouble urinating due to an enlarged prostate gland, a breathing problem such as emphysema or chronic bronchitis, glaucoma

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children
- drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- new symptoms occur
- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion gets worse or last more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present.
- 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

Overdose warning

in case of overdose, get medical help or contact a Poison Control Center right away (844) 832-1138. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions: do not take more than directed (see overdose warning)

Adults and children 12 years and over:

- take 2 tablets every 4-6 hours
- swallow whole - do not crush, chew or dissolve
- do not take more than 12 tablets in 24 hours

Children under 12 years: ask a doctor

OTHER INFORMATION

- Tamper evident. do not use if packet is torn, cut or opened
- Store at controlled room temperature 15° to 30°C (59° to 86°F)
- Avoid excessive heat and humidity

Inactive Ingredients

hydroxypropyl methylcellulose, methylcellulose, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, starch, stearic acid

Questions or comments? 619-600-5632

(Mon-Fri 9am - 5pm EST) or <https://www.facebook.com/republikrx/>

The carton has the complete information.

COLDTAC ULTRA
2 Tablets in a pouch

Drug Facts
 READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Active ingredients (in each tablet)
 Acetaminophen 325 mg
 Chlorpheniramine Maleate 2 mg
 Phenylephrine HCl 5 mg

Pain reliever
 Acetaminophen

Antihistamine
 Chlorpheniramine

Nasal decongestant
 Phenylephrine

Uses ■ temporarily relieves these symptoms of hay fever or other upper respiratory allergies: ■ headache ■ sinus congestion and pressure ■ nasal congestion ■ runny nose and sneezing ■ minor aches and pains ■ temporarily relieves these additional symptoms of hay fever: ■ itching of the nose or throat ■ itchy, watery eyes ■ helps clear nasal passages ■ helps decongest sinus openings and passages

Warnings - 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 alcoholic drinks every day while using this product

Major 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.

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.

■ if you have ever had an allergic reaction to this product or any of its ingredients ■ to make a child sleepy

Ask a doctor before use if you have
 ■ liver disease ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma

Ask a doctor or pharmacist before use if you are ■ taking the blood thinning drug warfarin ■ taking sedatives or tranquilizers ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma

When using this product ■ do not exceed recommended dosage ■ excitability may occur, especially in children ■ drowsiness may occur ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ avoid alcoholic drinks ■ be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if ■ new symptoms occur ■ nervousness, dizziness, or sleeplessness occur ■ pain or nasal congestion gets worse or lasts more than 3 days ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present. 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.** Attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Choose warnings in case of overdose, get medical help or contact a poison control center right away.

COLDTAC
ULTRA
 Tablets / Tabletas

Acetaminophen 325mg, Chlorpheniramine Maleate 2mg, Phenylephrine HCl 5mg

COLDTAC
 Tablets / Tabletas **ULTRA**

Exclusively distributed by
OPMX
 San Diego, CA 92154
 Phone: 619-600-5632

Made for
RX
 San Diego, CA



COLDTAC
 Tablets / Tabletas **ULTRA**
 Pain reliever, **Acetaminophen 325 mg**
 Antihistamine, **Chlorpheniramine Maleate 2 mg**
 Nasal decongestant, **Phenylephrine HCl 5 mg**

NDC 69517-142-06

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



- ◆ **Headache / Dolor de cabeza**
- ◆ **Nasal Congestion / Congestión nasal**
- ◆ **Itchy, Watery Eyes / Ojos llorosos**
- ◆ **Runny Nose & Sneezing / Escurrimiento nasal y Estornudos**

12 Tablets

75 mm
 2.952 in

Drug Facts (continued)
 Directions: do not take more than directed (see overdose warning)
 Adults and children 17 years and over ■ take 2 tablets every 4-6 hours ■ swallow whole - do not crush, chew or dissolve ■ do not take more than 12 tablets in 24 hours.
 Children under 17 years ask a doctor.

Inactive ingredients hydroxypropyl methylcellulose, methylcellulose, malbiodextrin, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, starch, stearic acid

Questions or comments? 619-600-5632 (Mon-Fri 9am-5pm EST) or <https://www.facebook.com/repultrix/>

Keep this carton—it has complete information.

DO NOT USE IF POUCH IS BROKEN OR TORN

30 mm
 1.184 in

85 mm
 3.351 in

Code No.: GUMPRUGS/GZ5F2025
 Batch #
 Exp. date
 NO VANISH AREA



Drug Facts (in each tablet)

Directions

Take 1 or 2 tablets every 4 to 6 hours as needed for pain or fever. Do not take more than 12 tablets in 24 hours.

Warnings

Do not take if you are allergic to any of the ingredients. Do not take if you have had an allergic reaction to any of the ingredients. Do not take if you have had an allergic reaction to any of the ingredients.

Directions

Take 1 or 2 tablets every 4 to 6 hours as needed for pain or fever. Do not take more than 12 tablets in 24 hours.

Warnings

Do not take if you are allergic to any of the ingredients. Do not take if you have had an allergic reaction to any of the ingredients. Do not take if you have had an allergic reaction to any of the ingredients.

COLDTAC
Tablets / Tabletas **ULTRA**

Cold & Flu Relief
Gripe y Resfriado

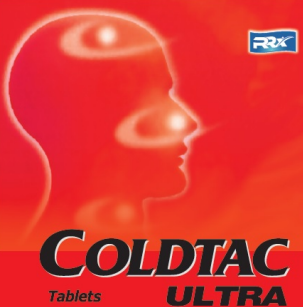
Pain reliever / Cuerpo cortado, Acetaminophen 325 mg
Antihistamine / Antihistaminico, Chlorpheniramine Maleate 2 mg
Nasal decongestant / Descongestivo nasal, Phenylephrine HCl 5 mg

COLDTAC
Tablets / Tabletas **ULTRA**

Cold & Flu Relief
Gripe y Resfriado

Tamper Evident
Unit Doze Packets
Empaquetado con Sellado
Evidente en Dosis Unitarias

144 Tablets | **72 packs**
2 tabs



COLDTAC
Tablets **ULTRA**

The Best
COLD & FLU
Relief Medicine



COLDTAC
Tabletas **ULTRA**

La mejor medicina
para el alivio de
LA GRIPE y
EL RESFRIADO

150 mm
5.934 in

87.3 mm
3.437 in

150 mm
5.934 in

87.3 mm
3.437 in

139.7 mm
5.5 in

COLDTAC ULTRA

acetaminophen 325mg, chlorpheniramine maleate 2mg, phenylephrine hcl 5mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-142
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-142-06	3 in 1 PACKAGE	01/05/2018	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:69729-142-72	72 in 1 PACKAGE	01/05/2018	
2		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 final	part341	01/05/2018	

Labeler - OPMX LLC (029918743)

Establishment

Name	Address	ID/FEI	Business Operations
Centurion Laboratories pvt. Ltd.		873229784	manufacture(69729-142) , analysis(69729-142) , pack(69729-142)

Revised: 1/2018

OPMX LLC