

**ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, PHENYLEPHRINE HCL-
acetaminophen, chlorpheniramine maleate, phenylephrine hcl 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 tabs
(Acetaminophen 500mg, Chlorpheniramine Maleate 4mg, Phenylephrine HCl 10mg Tablet)**

Acetaminophen 500mg

Chlorpheniramine Maleate 4mg

Phenylephrine HCl 10mg

Pain reliever/fever reducer

Antihistamine

Nasal decongestant

magnesium stearate, povidone, silicon dioxide, sodium benzoate, sodium starch glycolate, starch, talc

- Do not take more than directed - see overdose warning
- swallow whole; do not crush, chew or dissolve
- do not exceed 6 tablets per 24 hours

Adults and children 12 years of age & over	1 tablet with water every 4-6 hours as needed
Children 4 to 12 years of age	Ask a doctor
Children under 4 years of age	Do not use

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

- Headache
- Nasal congestion
- Sinus congestion & pressure
- Runny nose and sneezing
- Minor aches & pain

Temporarily relieves these additional symptoms of hay fever:

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

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

- more than 6 tablets in 24 hours, which is the maximum daily amount for this product
- with other drugs contains 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 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
- High blood pressure
- Thyroid disease
- Diabetes
- Trouble urinating due to enlarged prostate gland
- A breathing problem such as emphysema or chronic bronchitis

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

Pain, nasal congestion, or cough gets worse or lasts more than 7 days

Fever gets worse or last more than 3 days

Redness or swelling is present

New symptoms occur

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.

Keep out of reach of children.

OVERDOSE WARNING: Read directions carefully. In case of 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.

store at room temperature between 20-25°C (68-77°F)

avoid excessive heat and humidity

Uses: ■ temporarily relieves these symptoms of hay fever or other upper respiratory allergies ■ headache ■ sinus congestion & 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 6 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.

Directions:
 ■ Do not take more than directed - See Overdose warning
 ■ Swallow whole; do not crush, chew or dissolve
 ■ Do not exceed 6 tablets per 24 hours

Adults and children 12 years of age & over	1 tablet with water every 4-6 hours as needed
Children 4 to 12 years of age	Ask a doctor
Children under 4 years of age	Do not use

Other information: ■ Store at room temperature 20°-25°C (68°-77°F)
 ■ Avoid excessive heat and humidity

READ AND KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Exclusively distributed by:

 San Diego, CA 92154
 Phone: 619-496-2632

Made for:

 San Diego, CA

REV. 09/2019

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



New Formula

2 Tablets

Rx

COLDTAC

Tablets

ULTRA

ACTIVE INGREDIENTS (in each tablet) **PURPOSE**

Acetaminophen 500 mg.....Pain reliever/Fever reducer
 Chlorpheniramine Maleate 4 mg.....Antihistamine
 Phenylephrine HCl 10 mg.....Nasal decongestant

Effective and quick relief from cold & flu symptoms

- ◆ Headache
- ◆ Nasal Congestion
- ◆ Itchy, Watery Eyes
- ◆ Runny Nose & Sneezing



Children under 4 years of age	Do not use
Children 4 to 12 years of age	Ask a doctor
12 years of age & over	1 tablet with water every 4-6 hours as needed

Directions:

- Do not exceed 6 tablets per 24 hours
- Swallow whole, do not crush, chew or dissolve
- Do not take more than directed - See Overdose warning

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. Prompt medical attention is critical for adults as well as for children. Even if you do not notice any signs or symptoms.

Keep out of reach of children

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

Stop use and ask a doctor if: fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ new symptoms occur. These could be signs of a serious condition.

When using this product: ■ do not use more than directed ■ excitability may occur, especially in children ■ dizziness may occur ■ alcohol, sedatives and tranquilizers may increase drowsiness ■ avoid alcoholic drinks ■ be careful when driving a motor vehicle or operating machinery

Ask a doctor or a pharmacist before use if you are: ■ taking the blood thinning drug warfarin ■ taking sedatives or tranquilizers ■ diabetes ■ trouble urinating due to an enlarged prostate gland ■ a breathing problem such as emphysema or chronic bronchitis ■ taking a doctor before use if you have: ■ liver disease ■ heart disease ■ high blood pressure ■ thyroid disease ■ glaucoma ■ if you have ever had an allergic reaction to this product or any of its ingredients ■ to make a child sleep

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). If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking the product.

Warnings:

- 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

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). If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking the product.

Drug Facts

ACTIVE INGREDIENTS (in each tablet)

Acetaminophen 500 mg / Pain reliever/fever reducer

Chlorpheniramine Maleate 4 mg / Antihistamine

Phenylephrine HCl 10 mg / Nasal decongestant

Uses:

- temporarily relieves these symptoms of hay fever or other upper respiratory allergies ■ headache ■ sinus congestion & pressure ■ nasal congestion
- temporarily relieves runny nose and sneezing ■ minor aches and pains

Other Information: ■ Store at room temperature between 20°-25°C (68°-77°F) ■ Avoid excessive heat and humidity

Inactive ingredients: magnesium stearate, polydioxane, silicon dioxide, sodium benzoate, sodium starch glycolate, starch, talc

Questions or comments? Call (619) 600-6632 (Mon-Fri 9am-5pm EST) or <https://www.opvix.com>

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

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NDC 69729-122-37

COLDTAC
Tablets
ULTRA

Acetaminophen 500 mg / Pain reliever
Chlorpheniramine Maleate 4 mg / Antihistamine
Phenylephrine HCl 10 mg / Nasal decongestant

New Formula Effective and quick relief from cold & flu symptoms

Headache
Nasal Congestion
Itchy, Watery Eyes
Runny Nose & Sneezing

12 Tablets (6 Pouches of 2 Tablets)

8 56828 00841 0

56828 00841 0

OPVIX

San Diego, CA 92161
Phone: 619-600-6632

Manufactured by
OPVIX
San Diego, CA 92161
Phone: 619-600-6632

Made in USA

San Diego, CA 92161
Phone: 619-600-6632

Drug Facts (continued)

Other Information: ■ Store at room temperature between 20°-25°C (68°-77°F) ■ Avoid excessive heat and humidity

Inactive ingredients: magnesium stearate, polydioxane, silicon dioxide, sodium benzoate, sodium starch glycolate, starch, talc

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LOT

EXP. DATE



ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, PHENYLEPHRINE HCL

acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-122
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND (BICONVEX)	Size	13mm
Flavor		Imprint Code	S78
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-122-27	2 in 1 POUCH; Type 0: Not a Combination Product	08/26/2019	
2	NDC:69729-122-37	12 in 1 POUCH; Type 0: Not a Combination Product	08/26/2019	
3	NDC:69729-122-38	144 in 1 POUCH; Type 0: Not a Combination Product	08/26/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/26/2019	

Labeler - OPMX LLC (029918743)

Revised: 11/2020

OPMX LLC