

COLDTAC ULTRA- acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet
OPMX LLC

Coldtac Ultra

ACTIVE INGREDIENTS (in each tablet)

Acetaminophen 500 mg

Chlorpheniramine Maleate 4 mg

Phenylephrine HCl 10 mg

PURPOSE

Pain Reliever/Fever Reducer

Antihistamine

Nasal decongestant

Uses:

- temporarily relieves these symptoms of hay fever or other respiratory allergies:
- headache
- sinus congestion & pressure
- nasal congestion
- runny nose and sneezing
- minor aches & pain
- temporarily relieves these additional symptoms of hay fever:
- nose or throat itching
- itchy, watery eyes
- helps clear nasal passages
- helps decongest sinus opening and passages

Warnings

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.
- 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
- glaucoma
- 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
- taking sedatives or tranquilizers

When using this product:

- do not use more than directed
- 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:

- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion 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.

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.

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 between 20-25°C (68-77°F)
- Avoid excessive heat and humidity

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

Questions or comments?

Call: (619) 600-5632 (Mon-Fri 9am-5pm EST) or <https://www.opmx.us>

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

Exclusively distributed by:

OPMX

San Diego, CA 92154

Phone: 619-600-5632

PRINCIPAL DISPLAY PANEL - 144 TABLETS

NDC 69729-133-38

COLDTAC ULTRA

Actaminophen 500 mg, Chlorpheniramine Maleate 4 mg, Phenylephrine HCl 10 mg

Effective and Quick Relief from Cold & Flu Symptoms

Headache

Fever

Body Aches

Sneezing

Runny Nose

Watery Eye

Nasal Congestion

Sore Throat

144 Tablets (72 Packs of 2 tablets)



PRINCIPAL DISPLAY PANEL - 12 TABLETS

NDC 69729-133-38

COLDTAC ULTRA

Actaminophen 500 mg, Chlorpheniramine Maleate 4 mg, Phenylephrine HCl 10 mg

Effective and Quick Relief from Cold & Flu Symptoms

Headache

Fever

Body Aches

Sneezing

Runny Nose

Watery Eye

Nasal Congestion

Sore Throat

12 Tablets (6 Packs of 2 tablets)

COLDTAC
ULTRA Tablets / Tabletas

Drug Facts

Active Ingredients (in each tablet)

- Acetaminophen 500 mg
- Chlorpheniramine Maleate 4 mg
- Phenylephrine HCl 10 mg
- Antihistamine
- Nasal decongestant

Purpose

Temporarily relieves these symptoms of hay fever or other upper respiratory allergies: **headache**, **sinus congestion & pressure**, **nasal congestion**, **runny nose and sneezing**, **itchy, watery eyes**, **helps clear nasal passages**, **helps decongest sinuses**

Warnings **Live 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. If a skin reaction occurs, stop use and seek medical help right away.

Always read the acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, **hives**, **rash**. If a skin reaction occurs, stop use and seek medical help right away.

See blood warning: If sore throat is severe, persists for more than 7 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 (respiratory or non-respiratory), if you are not sure whether a drug contains acetaminophen ask a doctor or pharmacist. If you are now taking prescription monoamine oxidase inhibitor (MAOI) (certain drugs, antidepressants, or certain conditions or Parkinson's disease), for 2 weeks after stopping this 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 the product or any of its ingredients, do not take a child sleep.

Ask a doctor before use if you have: heart disease, **heart disease**, **high blood pressure**, **diabetes**, **glaucoma**, **thyroid disease**, **trouble urinating** due to an enlarged prostate gland or **avoid alcoholic drinks**.

When using this product: do not use more than directed. **Ask a doctor a pharmacist before use if you are:** taking the blood thinning drug warfarin, taking diabetes medications, **pregnant** or **breastfeeding**.

Stop use and ask a doctor if: nervousness, dizziness, or **sleepiness** occur. **Joint or nasal congestion** gets worse or lasts more than 7 days. **Ever gets worse or lasts more than 7 days**.

Keep out of reach of children. **Child-resistant 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. From a medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

NO VANISH AREA

Batch # _____

Exp. date _____

CODE: GUV/DRUGS/G/25/2644

COLDTAC
ULTRA

Effective and quick relief from cold & flu symptoms

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

Contents **12** Tablets
Contenido **12** Tabletas

COLDTAC
ULTRA

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

NDC 69729-133-37

Made for: **RPX**
San Diego, CA

Rev. 01/2024 Item # REX1073
568281008410

Exclusively distributed by: **OPMX**
Chula Vista, CA 91910
Phone: 619-600-5532

CONSULTE LA INFORMACION COMPLETA EN ESPAÑOL EN EL INTERIOR DE LA GALIA

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

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

Questions or comments? Call: (619) 600-5532 (Mon-Fri 9am-5pm EST) or <http://www.opmx.us>

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

Drug Facts (continued)

Adults and children 12 years of age & over 1 tablet with water every 4 to 6 hours as needed

Children 6 to 12 years of age Ask a doctor

Children under 6 years of age Do not use

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

PRINCIPAL DISPLAY PANEL - 6 TABLETS

NDC 69729-133-06

COLDTAC ULTRA

Actaminophen 500 mg, Chlorpheniramine Maleate 4 mg, Phenylephrine HCl 10 mg

Effective and Quick Relief from Cold & Flu Symptoms

Headache

Fever

Body Aches

Sneezing

Runny Nose

Watery Eye

Nasal Congestion

Sore Throat

6 Tablets (3 Packs of 2 tablets)



NO VANISH AREA

CODE: GUM/DRUGS/G/25/2644

LOT

EXP. DATE

Drug Facts

Active ingredients (in each tablet)

Acetaminophen 500 mg Pain reliever

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 ■ runny nose and sneezing ■ minor aches and pains ■ temporarily relieves these additional symptoms of hay fever: ■ nose or throat itching ■ 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 redness ■ 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 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 ■ thyroid disease ■ glaucoma ■ diabetes ■ trouble urinating due to an enlarged prostate gland ■ a breathing problem ■ thinning drug warfarin ■ taking sedatives or tranquilizers ■ do not use more than directed ■ excitability may occur, especially in children ■ alcohol, sedatives and tranquilizers may increase drowsiness ■ avoid alcoholic drinks ■ be careful when driving a motor vehicle or operating machinery ■ use and ask a doctor if: ■ nervousness, dizziness, or sleepiness occur ■ pain or nasal congestion gets 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. ■ pregnant or breast-feeding: ask a health professional before use. ■ **Keep out of reach of children.** Overdose warning: Taking more than directed can cause serious health problems. 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 ■ Swallow whole; do not crush, chew or dissolve ■ Do not exceed 6 tablets per 24 hours

Adults and children	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 between 20° - 25°C (68° - 77°F) ■ Avoid excessive heat and humidity ■ Inactive ingredients: magnesium stearate, povidone, silicon dioxide, sodium benzoate, sodium starch glycolate, starch, talc

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

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

PRINCIPAL DISPLAY PANEL - 2 TABLETS

NDC 69729-133-27

COLDTAC ULTRA

Actaminophen 500 mg, Chlorpheniramine Maleate 4 mg, Phenylephrine HCl 10 mg

Effective and Quick Relief from Cold & Flu Symptoms

Headache

Fever

Body Aches

Sneezing

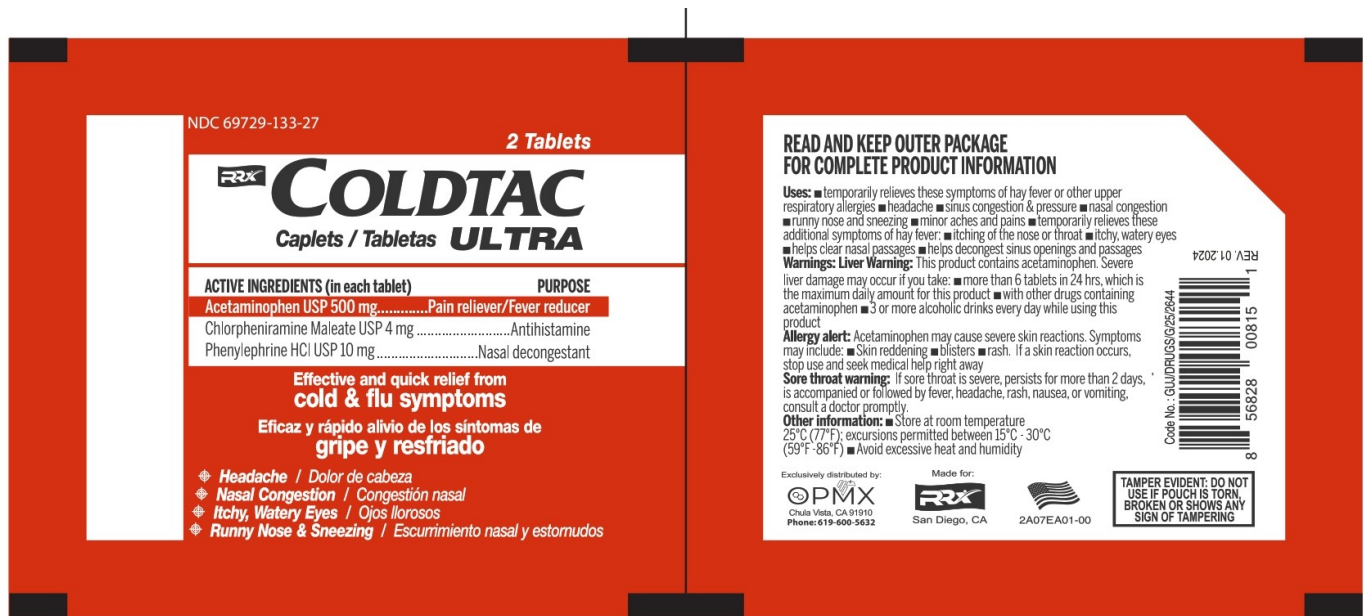
Runny Nose

Watery Eye

Nasal Congestion

Sore Throat

2 Tablets



COLDTAC ULTRA

acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-133
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TALC (UNII: 7SEV7J4R1U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	13mm
Flavor		Imprint Code	A15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-133-38	72 in 1 CARTON	01/10/2024	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:69729-133-37	6 in 1 CARTON	01/10/2024	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:69729-133-06	3 in 1 CARTON	01/10/2024	
3		2 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:69729-133-27	2 in 1 POUCH; Type 0: Not a Combination Product	01/10/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/10/2024	

Labeler - OPMX LLC (029918743)

Establishment

Name	Address	ID/FEI	Business Operations
Vovantis Laboratories Private Limited		650502151	manufacture(69729-133)

Revised: 1/2024

OPMX LLC