

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

Healthlife of USA

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

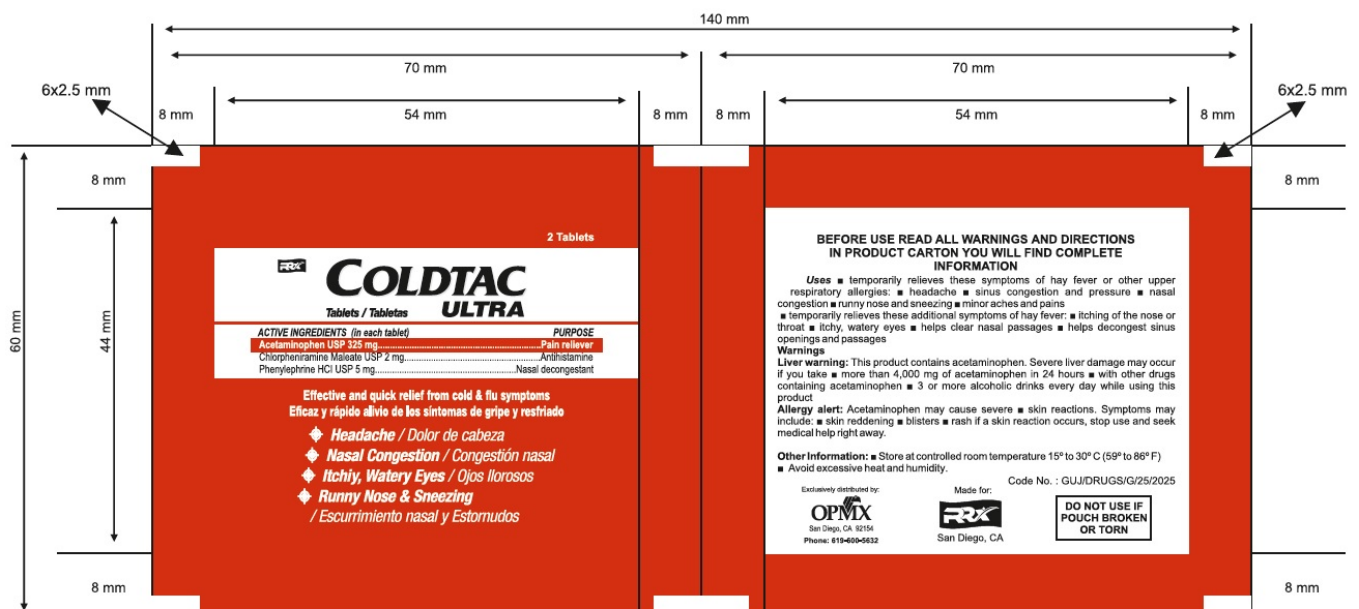
hydroxypropyl methylcellulose, methylcellulose, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, starch, stearic acid

Questions or comments? 619-600-5632

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

The carton has the complete information.

COLDTAC ULTRA 2 Tablets in a pouch



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 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
MALTO DEXTRIN (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:69517-142-06	3 in 1 PACKAGE	10/02/2017	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:69517-142-72	36 in 1 PACKAGE	10/02/2017	
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	10/02/2017	

Labeler - Healthlife of USA (079656178)

Establishment

Name	Address	ID/FEI	Business Operations
Centurion Laboratories pvt. Ltd.		873229784	manufacture(69517-142) , analysis(69517-142) , pack(69517-142)