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)

Drug Facts

Active ingredients

Purpose

Active ingredients (in each caplet)	***Purpose***
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 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

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,
- 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
- 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 ot pharmacist 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 alcohol drinks
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if:

- nervousness, dizziness, or sleeplessness occur
- 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.

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 (68-77ºF)
- Tamper evident: Do not use if pouch is torn, broken or shows any sing of tampering

Inactive ingredients

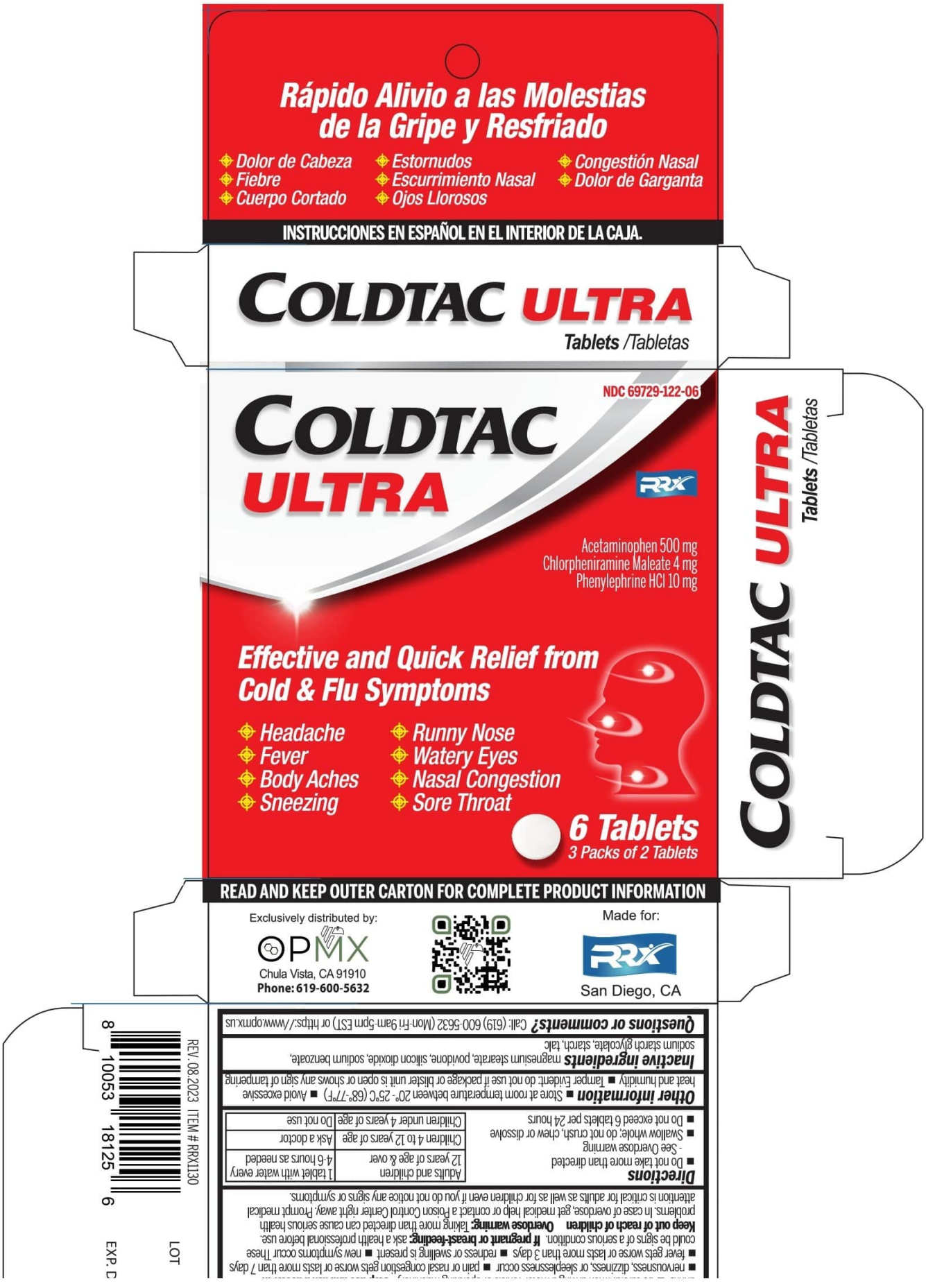
magnesium stearate, povidone, silicon dioxide, sodium benzoate, sodium starch glycolate, starch, talc

Questions or comments?

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

Coldtac Ultra

NDC 69729-122-06



Drug Facts

Active ingredients (in each caplet)	Purpose
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: ■ itching of the nose or throat ■ itchy, watery eyes ■ helps clear nasal passages ■ helps decongest sinus openings and passages ■ bloating ■ water-weight gain ■ headache ■ backache ■ muscle aches ■ fatigue

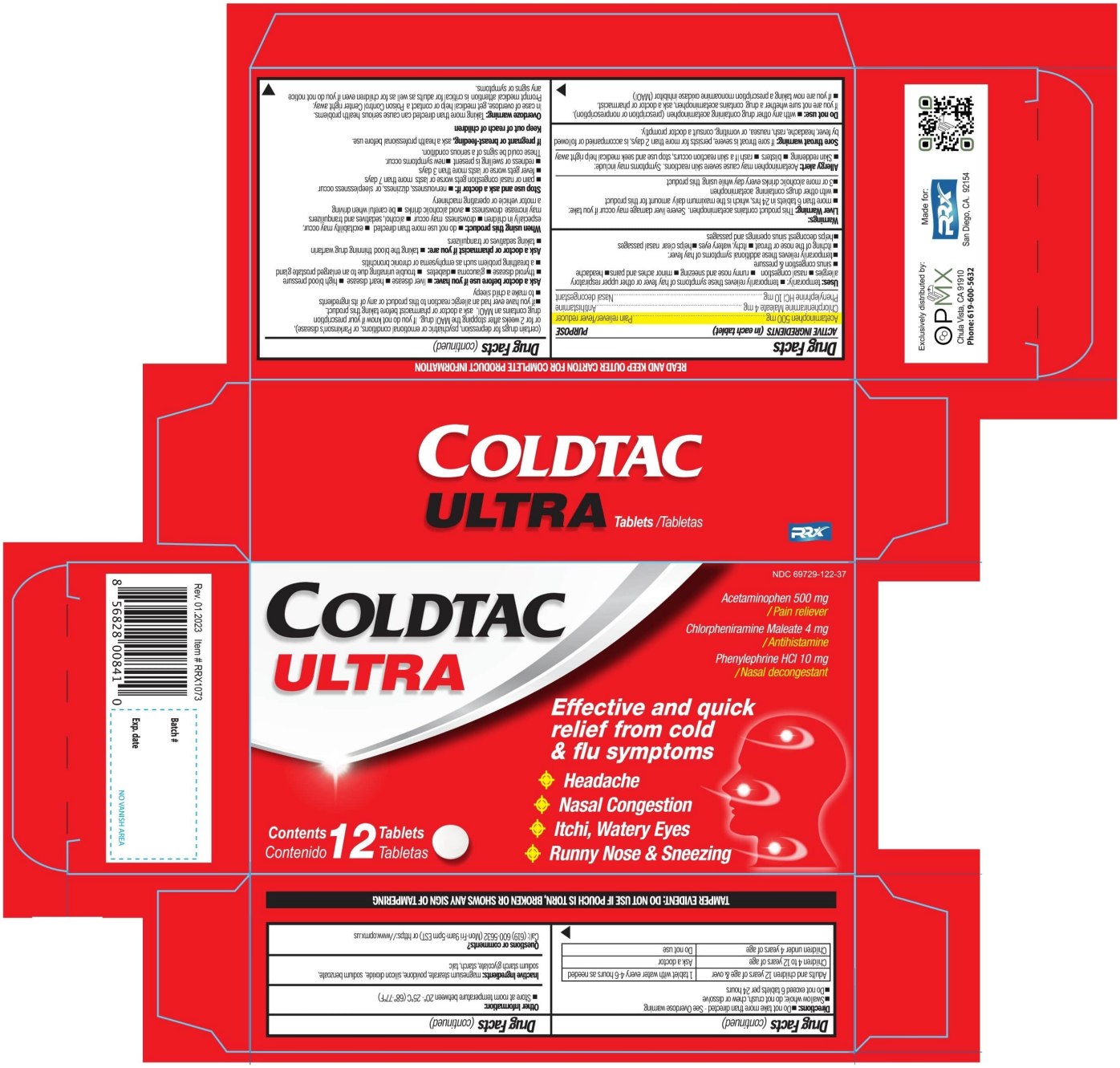
Warnings Liver warning: Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take: ■ more than 6 tablets in 24 hrs, which is the maximum daily amount for this product ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this 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.

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 an enlarged prostate gland ■ a breathing problem such as emphysema or chronic bronchitis **Ask a doctor or a 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:**

NDC 69729-122-37



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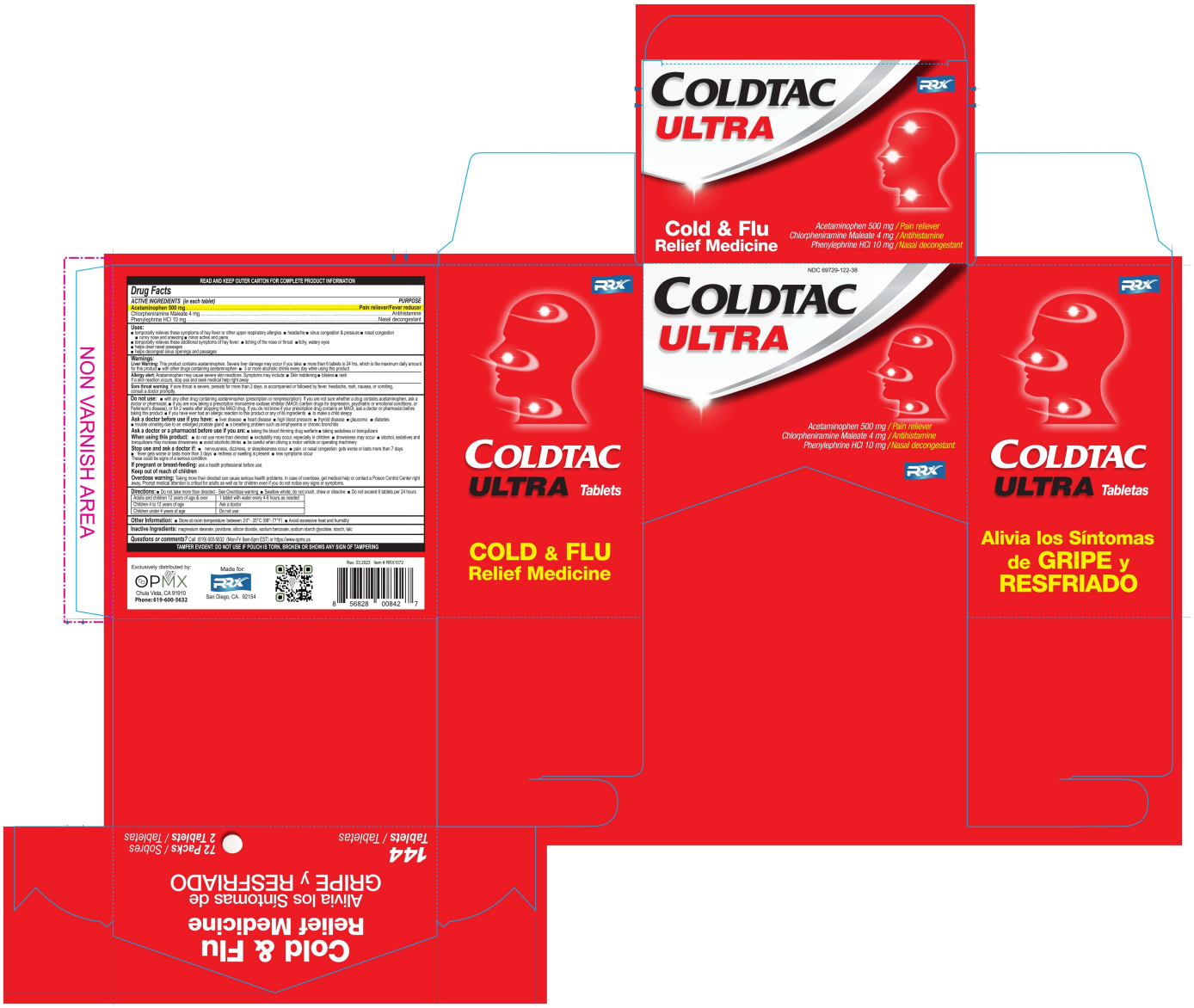

ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, PHENYLEPHRINE HCL

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	10/24/2022
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	
4	NDC:69729-122-06	3 in 1 CARTON	09/04/2023	
4		2 in 1 PACKET; 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	08/26/2019	

Labeler - OPMX LLC (029918743)

Revised: 9/2023 OPMX LLC