

**RESFRIOL D- acetaminophen, chlorpheniramine maleate, phenylephrine  
hcl tablet  
OPMX LLC**

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**RESFRIOL D**

***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

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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

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**Other information:**

- Store at room temperature between 20-25°C (68-77°F); excursions permitted between 15°C - 30°C (59°F - 86°F)
- Avoid excessive heat and humidity
- Tamper Evident: do not use if package or blister unit is open or shows any sign of tampering.

**Inactive ingredients:** Microcrystalline cellulose, Polyvinylpyrrolidone, Croscopovidone, Magnesium stearate, Colloidal silicon dioxide, Purified talc

**Questions or comments?**

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

Exclusively distributed by:

OPMX

San Diego, CA 92154

**Phone: 619-600-5632**

**PRINCIPAL DISPLAY PANEL - 144 TABLETS**

NDC 69729-323-38

RESFRIOL D

Actaminophen 500 mg - Pain reliever/Fever Reducer

Chlorpheniramine Maleate 4 mg - Antihistamine

Phenylephrine HCl 10 mg - Nasal decongestant

Cold/Allergy Relief

To relieve common symptoms of Cold & Allergy such as:

Headache

Sneezing

Nasal Congestion

# Itchy, Watery Eyes and Runny Nose

## 144 Tablets (72 Pouches of 2 tablets)



### PRINCIPAL DISPLAY PANEL - 12 TABLETS

NDC 69729-323-37

RESFRIOL D

Actaminophen 500 mg - Pain reliever/Fever Reducer

Chlorpheniramine Maleate 4 mg - Antihistamine

Phenylephrine HCl 10 mg - Nasal decongestant

Cold/Allergy Relief

To relieve common symptoms of Cold & Allergy such as:

Headache

Sneezing

Nasal Congestion

Itchy, Watery Eyes and Runny Nose



## PRINCIPAL DISPLAY PANEL - 2 Tablets

NDC 69729-323-27

RESFRIOL D

Actaminophen 500 mg - Pain reliever/Fever Reducer

Chlorpheniramine Maleate 4 mg - Antihistamine

Phenylephrine HCl 10 mg - Nasal decongestant

Cold/Allergy Relief

To relieve common symptoms of Cold & Allergy such as:

Headache

Sneezing

Nasal Congestion

Itchy, Watery Eyes and Runny Nose

2 Tablets



## RESFRIOL D

acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69729-323
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>CROSPROVIDONE, UNSPECIFIED</b> (UNII: 2S7830E561)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	A15
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-323-38	72 in 1 CARTON	01/10/2024	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:69729-323-37	6 in 1 CARTON	01/10/2024	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:69729-323-27	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(69729-323)

Revised: 1/2024

OPMX LLC