

**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.

Resfriol D

(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



RESFRIOL D



144 TABLETS **New Formula**

READ AND KEEP PATIENTS CAUTION FOR COMPLETE PRODUCT INFORMATION

Drug Facts

IMPORTANT INFORMATION: For best results, RESFRIOL D should be taken with food.

Directions: Take 1 or 2 tablets 2 to 3 times a day. Do not exceed 6 tablets in 24 hours. For children 12 years of age and younger, ask your healthcare provider for directions. For children younger than 12 years, do not use without a doctor's advice.

Warnings: Do not take RESFRIOL D if you are allergic to any of the ingredients. Do not take RESFRIOL D if you are taking other medicines that contain pseudoephedrine, phenylephrine, or dextroamphetamine. Do not take RESFRIOL D if you are taking MAO inhibitors or MAO inhibitor diet pills. Do not take RESFRIOL D if you are taking aspirin, ibuprofen, or other NSAIDs. Do not take RESFRIOL D if you are taking SSRIs, SNRIs, or MAO inhibitors. Do not take RESFRIOL D if you are pregnant, planning to get pregnant, or breastfeeding. Do not take RESFRIOL D if you are taking grapefruit juice. Do not take RESFRIOL D if you are taking MAO inhibitors or MAO inhibitor diet pills. Do not take RESFRIOL D if you are taking aspirin, ibuprofen, or other NSAIDs. Do not take RESFRIOL D if you are taking SSRIs, SNRIs, or MAO inhibitors. Do not take RESFRIOL D if you are pregnant, planning to get pregnant, or breastfeeding. Do not take RESFRIOL D if you are taking grapefruit juice.



Made for:

OPIMX
San Diego, CA 92161
Phone: 619-595-5611



RESFRIOL D
Cold/Allergy Relief

New Formula FOLD 144 TABLETS 72 Pouches of 2 TABLETS
NDC 69720122-38

RESFRIOL D **BLUE**
Acetaminophen, Pseudoephedrine HCl, Diphenhydramine HCl, Lorazepam, and First Generation Antihistamines

To relieve common symptoms of cold & allergy such as:
Headache
Nasal Congestion
Sneezing
Itchy, Watery Eyes and Runny Nose

Cold/Allergy Relief
144 TABLETS:
72 Pouches of 2 TABLETS

RESFRIOL D
Cold/Allergy Relief

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

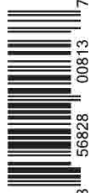
READ AND KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Exclusively distributed by:
OPMX
San Diego, CA 92164
Phone: 619-496-6432

Made for:
RX
San Diego, CA

REV 092019

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



New Formula

2 Tablets

RESFRIOL[®] D

ACTIVE INGREDIENTS (in each tablet)

PURPOSE

Acetaminophen 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



ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, PHENYLEPHRINE

HCL

acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-322
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:69729-322-27	2 in 1 POUCH; Type 0: Not a Combination Product	08/26/2019	
2	NDC:69729-322-37	12 in 1 POUCH; Type 0: Not a Combination Product	08/26/2019	
3	NDC:69729-322-38	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	

