

ALLERGY- acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet

L. Perrigo Company

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.

Perrigo Allergy Drug Facts

Active ingredients (in each caplet)

Acetaminophen 325 mg

Chlorpheniramine maleate 2 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever

Antihistamine

Nasal decongestant

Uses

- temporarily relieves these symptoms of hay fever or other upper respiratory allergies:
- runny nose and sneezing
- nasal congestion
- minor aches and pains
- headache
- sinus congestion and pressure
- 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. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. 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

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
- diabetes
- high blood pressure
- thyroid disease
- 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
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- drowsiness may occur

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion gets worse or lasts more than 7 days
- new symptoms occur
- 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.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) 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 Liver warning)

adults and children 12 years and over	<ul style="list-style-type: none">take 2 caplets every 4-6 hoursswallow whole – do not crush, chew or dissolvedo not take more than 10 caplets in 24 hours
children under 12 years	ask a doctor

Inactive ingredients

acesulfame potassium, carnauba wax, flavor, iron oxide yellow, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

See New Warnings and Directions

Compare to Tylenol® Allergy Multi-Symptom active ingredients

FOR ADULTS

allergy

Multi-Symptom

Acetaminophen, Chlorpheniramine Maleate, Phenylephrine HCl

PAIN RELIEVER, NASAL DECONGESTANT, ANTIHISTAMINE

Headache

Nasal Congestion

Sinus Pressure

Runny Nose/Sneezing

Itchy, Watery Eyes

24 Cool Ice® CAPLETS

<p>Drug Facts (continued)</p> <p>Uses ■ temporarily relieves these symptoms of hay fever or other upper respiratory allergies:</p> <ul style="list-style-type: none"> ■ runny nose and sneezing ■ nasal congestion ■ minor aches and pains ■ headache ■ sinus congestion and pressure 	<p>Drug Facts</p> <p>Active Ingredients (in each caplet)</p> <p>Pain reliever Acetaminophen 325 mg.....</p> <p>Antihistamine Chlorpheniramine maleate 2 mg.....</p> <p>Nasal decongestant Phenylephrine HCl 5 mg.....</p>
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NDC 0113-2476-62
**See New Warnings
and Directions**

Compare to Tylenol® Allergy
Multi-Symptom
active ingredients*

FOR ADULTS

allergy

Multi-Symptom

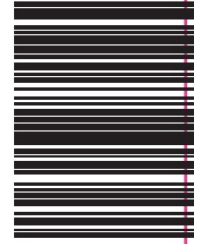
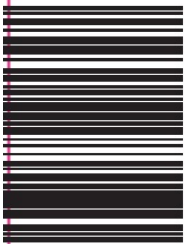
Acetaminophen, Chlorpheniramine Maleate,
Phenylephrine HCl

**PAIN RELIEVER, NASAL DECONGESTANT,
ANTI-HISTAMINE**

- Headache
- Nasal Congestion
- Sinus Pressure
- Runny Nose/Sneezing
- Itchy, Watery Eyes



24 Cool Ice®
CAPLETS



47662 55 CT

Drug Facts (continued)

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Gluten Free

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN
Store between 20-25°C (68-77°F).

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Allergy Multi-Symptom.

Distributed By **Perrigo**® Allegan, MI 49010 perrigo.com

Drug Facts (continued)

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Questions or comments? 1-800-719-9260



ALLERGY

acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0113-2476
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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 HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	WHITE (off white)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor	VANILLA (Vanilla-menthol)	Imprint Code	L476
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0113-2476-62	12 in 1 CARTON	03/20/2014	
1		2 in 1 BLISTER PACK; 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	03/20/2014	

Labeler - L. Perrigo Company (006013346)

Revised: 12/2019

L. Perrigo Company