

LEADER COLD RELIEF- acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet, film coated
Cardinal Health 110, LLC. dba Leader

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.

Cardinal Health Cold Relief Drug Facts

Active ingredients (in each caplet)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves these common cold/flu symptoms:
- minor aches and pains
- headache
- sore throat
- nasal congestion
- cough
- sinus congestion and pressure
- helps clear nasal passages
- promotes nasal and sinus drainage
- temporarily reduces fever

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.

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

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
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

When using this product

do not exceed recommended dosage

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 lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts

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 (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 overdose warning)

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

Inactive ingredients

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

Questions or comments?

1-800-719-9260

Principal Display Panel

Non-Drowsy | Daytime

Cold Relief

Acetaminophen | Dextromethorphan HBr | Phenylephrine HCl

Pain Reliever / Fever Reducer | Cough Suppressant | Nasal Decongestant

Headache, Fever, Sore Throat,

Nasal Congestion, Cough

For Adults

COMPARE TO TYLENOL® COLD MAX active ingredients

24 CAPLETS

Actual Size

100% Money Back Guarantee



CODE AREA

37162 E9 C2

Drug Facts (continued)

Directions ■ Do not take more than directed (see over dose warning)

12 years and over

- Take 2 caplets every 4 hours
- Swallow whole - do not crush, chew or dissolve
- Do not take more than 10 caplets in 24 hours

Children under 12 years ask a doctor

Drug Facts (continued)

Inactive Ingredients acetaminophen, aspirin, caffeine, wax, croscarmellose, hydroxypropyl methylcellulose, polyethylene glycol, polyvinyl alcohol, polyvinylpyrrolidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Questions or comments? 1-800-719-9260

Shop at 20-25¢ (68-77¢) **Gluten Free**

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Phenylephrine HCl 5 mg

Purposes

Pain reliever/fever reducer
Cough suppressant
Nasal decongestant

Uses

- temporarily relieves these common cold/flu symptoms:
 - sore throat
 - headache
 - sore throat
 - nasal congestion and pressure
 - sinus congestion
 - runny nose
 - throat irritation
 - nasal and sinus drainage
- temporarily reduces fever

Warnings

Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours

- 3 or more alcoholic drinks a very day while using this product
- with other drugs containing acetaminophen

Do not use

- with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Some throat lozenges, pastilles, or more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Keep out of reach of children. Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Use caution when driving or operating machinery. Do not take more than 10 caplets in 24 hours.

When using this product do not exceed recommended dosage

Stop use and ask a doctor if

- pain, nasal congestion or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling persists or worsens with use
- cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition.

If pregnant or breastfeeding, 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 (1-800-222-1222). Use caution when driving or operating machinery. Do not take more than 10 caplets in 24 hours.

Drug Facts (continued)

Warnings

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

Ask a doctor before use if you have

- liver disease
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CIN 5294343 REV. 5/17

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F. BROKEN OR TORN RETURN TO STORE.

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Important: Read all product information before using. Keep this box for important information.

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Non-Drowsy | Daytime Cold Relief

Acetaminophen | Dextromethorphan HBr | Phenylephrine HCl
Pain Reliever / Fever Reducer | Cough Suppressant | Nasal Decongestant

Headache, Fever, Sore Throat, Nasal Congestion, Cough
For Adults

24 CAPLETS  Actual Size

COMPARE TO TYLENOL® COLD MAX active ingredients*

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LEADER COLD RELIEF

acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0168
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 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)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
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)	

Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE (caplet)	Size	17mm
Flavor	VANILLA ((menthol))	Imprint Code	L371
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0168-1	12 in 1 CARTON	12/07/2016	
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	12/07/2016	

Labeler - Cardinal Health 110, LLC. dba Leader (063997360)

Revised: 6/2021

Cardinal Health 110, LLC. dba Leader