

**SEVERE COLD AND FLU- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated**  
**Cardinal Health 110, LLC. DBA Leader**

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**Leader 44-503A**

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

Acetaminophen 325 mg  
Dextromethorphan HBr 10 mg  
Guaifenesin 200 mg  
Phenylephrine HCl 5 mg

***Purpose***

Pain reliever/fever reducer  
Cough suppressant  
Expectorant  
Nasal decongestant

***Uses***

- temporarily relieves these common cold and flu symptoms:
  - sore throat
  - cough
  - nasal congestion
  - headache
  - minor aches and pains
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- 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**

- heart disease
- liver disease
- diabetes
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- thyroid disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland

**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
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- 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.**

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**
- adults and children 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

### ***Other information***

- **each caplet contains:** sodium 3 mg
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

### ***Inactive ingredients***

corn starch, crospovidone, D&C yellow #10 aluminum lake, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

### ***Questions or comments?***

**1-800-426-9391**

### ***Principal display panel***

**LEADER♥™**

NDC 70000-0525-1

### **Severe Cold & Flu**

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

Headache, Fever, Sore Throat,  
Nasal Congestion, Cough, Mucus,  
Chest Congestion

24 CAPLETS

Actual Size

**COMPARE TO TYLENOL®**  
**COLD + FLU SEVERE**  
active ingredients†

100% Money Back Guarantee

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS  
OPENED OR IF BLISTER UNIT IS TORN, BROKEN  
OR SHOWS ANY SIGNS OF TAMPERING**

†This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol® COLD + FLU SEVERE.  
50844 REV0922A50308

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✓ **100%**  
**Money Back**  
**Guarantee**

Return to place of purchase.

CIN 5564372 REV.2/23

**PARENTS:**

Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

**Directions** ■ do not take more than directed  
 ■ adults and children 12 years and over  
 ■ take 2 caplets every 4 hours  
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 ■ swallow whole - do not crush, chew, or dissolve  
 ■ children under 12 years: ask a doctor

**Warnings** (continued)  
 ■ heart disease ■ liver disease ■ diabetes  
 ■ cough that occurs with too much phlegm (mucus)  
 ■ Ask a doctor before use if you have

**Drug Facts** (continued)  
 ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ thyroid disease ■ high blood pressure ■ difficulty in urination due to enlargement of the prostate gland  
 ■ 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 sleepiness occur  
 ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days  
 ■ new symptoms occur  
 ■ liver gets worse or lasts more than 3 days  
 ■ redness or swelling is present  
 ■ 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. 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.

**Drug Facts** (continued)  
 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 redness ■ hives ■ 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, 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.  
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**Ask a doctor before use if you have**  
 ■ heart disease ■ liver disease ■ diabetes  
 ■ cough that occurs with too much phlegm (mucus)

**Drug Facts** (continued)  
 ■ temporarily relieves these common cold and flu symptoms: ■ sore throat ■ cough ■ nasal congestion ■ headache  
 ■ minor aches and pains  
 ■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive ■ temporarily reduces fever

**Drug Facts** (continued)  
 ■ temporarily relieves these common cold and flu symptoms:  
 ■ sore throat ■ cough ■ nasal congestion ■ headache  
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**Drug Facts**  
 KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

**Active Ingredients (in each caplet)**  
 Acetaminophen 325 mg  
 Dextromethorphan HBr 10 mg  
 Cough suppressant  
 Pain reliever/fever reducer

**Purpose**  
 Expectorant  
 Nasal decongestant  
 Phenylephrine HCl 5 mg  
 Guaifenesin 200 mg

100% Money Back Guarantee  
 Return to place of purchase.  
 PARENTS: www.tylenol.com  
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NDC 70000-0525-1

**LEADER**

# Severe Cold & Flu

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

Headache, Fever, Sore Throat,  
 Nasal Congestion, Cough, Mucus,  
 Chest Congestion

**24 CAPLETS**

Actual Size

**COMPARE TO TYLENOL® COLD + FLU SEVERE**  
 active ingredients<sup>†</sup>  
 100% Money Back Guarantee

**Drug Facts** (continued)  
 ■ each caplet contains: sodium 3 mg  
 ■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BUSTER IS TORN OR BROKEN  
 ■ see end flap for expiration date and lot number  
 ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

**Other Information**  
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**Questions or comments?** 1-800-426-9391

**Drug Facts** (continued)  
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 ©2023 Cardinal Health. All rights reserved. CARDINAL HEALTH, the Cardinal Health logo, LEADER, and the LEADER logo are trademarks or registered trademarks of Cardinal Health. All other marks are the property of their respective owners.

No print/No varnish  
 Lot & Exp date

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BUSTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

CIN 5564372 REV. 2/23  
 0 96295 13860 3

Leader 44-503A

**SEVERE COLD AND FLU**  
 acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0525
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSPVIDONE, UNSPECIFIED</b> (UNII: 2S7830E561)	
<b>D&amp;C YELLOW NO. 10 ALUMINUM LAKE</b> (UNII: CQ3XH3DET6)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>	MENTHOL	<b>Imprint Code</b>	44;503
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:70000-0525-1	2 in 1 CARTON	10/25/2019	
1		12 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 Drug	M012	10/25/2019	

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

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70000-0525) , pack(70000-0525)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(70000-0525)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70000-0525)

Revised: 3/2025

Cardinal Health 110, LLC. DBA Leader