

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

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

LEADERTM

NDC 70000-000-0525-1

Severe Cold & Flu

Acetaminophen | Dextromethorphan HBr
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Nasal Congestion, Cough, Mucus,
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24 CAPLETS

Actual Size

COMPARE TO TYLENOL[®]
COLD + FLU SEVERE
active ingredients[†]

100% Money Back Guarantee

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



3

100%
Money Back
Guarantee

Return to place of purchase.

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DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43007

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B-0225-503A-0865F
REV082451008

Drug Facts (continued)

Warnings 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 ■ 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 over-the-counter). 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)

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.

Directions ■ do not take more than directed ■ adults and children 12 years and over ■ take 2 caplets every 4 hours ■ do not take more than 10 caplets in 24 hours ■ children under 12 years: ask a doctor

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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Drug Facts (continued)

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

Drug Facts (continued)

Other information ■ 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)

Inactive ingredients corn starch, croscapellone, 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

Leader 44-503A

SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0525
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: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

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

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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: 3/2024

Cardinal Health 110, LLC. DBA Leader