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

Leader 44-640 Delisted

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 common cold and flu symptoms:
- minor aches and pains
- sinus congestion and pressure
- sore throat
- fever
- headache
- nasal congestion
- cough due to minor throat and bronchial irritation
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

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:

- blisters
- rash
- skin reddening

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

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.

In case of accidental 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**
- do not take more than 8 caplets in 24 hours
- adults and children 12 years and over: take 2 caplets with water every 4 hours
- children under 12 years: ask a doctor

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal display panel

LEADER™

NDC 70000-0289-1

Daytime ι Non-Drowsy

Severe Cold & Flu

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

Relief of:
Headache, Fever, Sore Throat, Minor Aches & Pains,
Nasal/Sinus Congestion & Sinus Pressure,
Cough, Chest Congestion

12 CAPLETS

Actual Size

COMPARE TO VICKS® DAYQUIL®
SEVERE COLD & FLU
active ingredients*

100% Money
Back Guarantee

*This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademark Vicks® DayQuil® Severe Cold & Flu.

50844 REV0519B64002

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

CIN 5326152 REV. 11/21

CardinalHealth™

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6313
Essential to Care™ since 1979

All LEADER™ Brand Products Have A
100% Money Back Guarantee
Return to place of purchase if not satisfied.

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

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Drug Facts (continued)

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Drug Facts (continued)

Questions or comments? 1-800-426-9391

*This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademark Vicks® DayQuil® Severe Cold & Flu.

50844 REV0519B64002

B-0225-640-02
REV0519B64002

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

no print / no varnish area
lot no. & exp. date

CIN 5326152
REV. 11/21

0 96295 13182 6

100% Money Back Guarantee

COMPARE TO VICKS® DAYQUIL® SEVERE COLD & FLU active ingredients*

Actual Size

12 CAPLETS

Relief Of:
Headache, Fever, Sore Throat, Minor Aches & Pains, Nasal/Sinus Congestion & Sinus Pressure, Cough, Chest Congestion

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PARENTS: Learn about teen medicine abuse www.StopMedicineAbuse.org

LEADER™

NDC 70000-0289-1

Daytime | Non-Drowsy

Severe Cold & Flu

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

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Drug Facts

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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- sore throat ■ fever ■ headache ■ nasal congestion
- cough due to minor throat and bronchial irritation
- reduces swelling of nasal passages

Drug Facts (continued)

Leader 44-640

SEVERE COLD AND FLU MAXIMUM STRENGTH, DAYTIME, NON-DROWSY

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

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0289
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)	
CROSPOVIDONE (UNII: 2S7830E561)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
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)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	44;640

Contains

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0289-1	1 in 1 CARTON	02/27/2014	01/31/2025
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	02/27/2014	01/31/2025

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

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70000-0289) , pack(70000-0289)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(70000-0289)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70000-0289)

Revised: 12/2023 Cardinal Health 110, LLC. DBA Leader