

**SEVERE COUGH AND CONGESTION AND COLD AND FLU DAYTIME, NIGHTTIME-
acetaminophen, dextromethorphan hbr, diphenhydramine hcl, guaifenesin,
phenylephrine hcl
Meijer Distribution Inc**

Meijer 44-648694 Clamshell Delisted

***Active ingredients (in each caplet)
(Daytime Severe Congestion & Cough)***

Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Purpose

Cough suppressant
Expectorant
Nasal decongestant

Active ingredients (in each caplet) (Nighttime Cold & Flu)

Acetaminophen 325 mg
Diphenhydramine HCl 12.5 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Antihistamine/cough suppressant
Nasal decongestant

Uses (Daytime only)

- temporarily relieves:
 - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
 - nasal congestion due to a cold
 - the intensity of coughing
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Uses (Nighttime only)

- temporarily relieves these common cold and flu symptoms:
 - headache

- sore throat
- nasal congestion
- runny nose and sneezing
- cough
- minor aches and pains
- temporarily reduces fever
- controls cough to help you get to sleep

Warnings (Nighttime only)

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- with other drugs containing acetaminophen
- more than 4,000 mg of acetaminophen in 24 hours
- 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

- 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.
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. **(Nighttime only)**
- if you have ever had an allergic reaction to this product or any of its ingredients **(Nighttime only)**
- with any other product containing diphenhydramine, even one used on skin **(Nighttime only)**

Ask a doctor before use if you have

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

- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis (**Nighttime only**)
- glaucoma (**Nighttime only**)
- liver disease (**Nighttime only**)

Ask a doctor or pharmacist before use if you are (Nighttime only**)**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizer

When using this product

- **do not exceed recommended dosage**
- excitability may occur, especially in children (**Nighttime only**)
- alcohol, sedatives, and tranquilizers may increase drowsiness (**Nighttime only**)
- be careful when driving a motor vehicle or operating machinery (**Nighttime only**)
- avoid alcoholic beverages (**Nighttime only**)
- marked drowsiness may occur (**Nighttime only**)

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not get better within 7 days or occur with fever (**Daytime only**)
- redness or swelling is present (**Nighttime only**)
- pain, nasal congestion, or cough gets worse or lasts more than 7 days (**Nighttime only**)
- new symptoms occur (**Nighttime only**)
- fever gets worse or lasts more than 3 days (**Nighttime only**)
- 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.

Do not take DAYTIME and NIGHTTIME products at the same time.

Directions

- **do not use more than directed**
- do not take more than 12 caplets in any 24-hour period
- adults and children 12 years and over: take 2 caplets every 4 hours
- children under 12 years: do not use

Other information

- **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)
- use by expiration date on package

Inactive ingredients (Daytime only)

corn starch, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Inactive ingredients (Nighttime only)

corn starch, croscarmellose sodium, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, iron oxide yellow, magnesium stearate, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium bicarbonate, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

COMBO PACK

Total 30 Caplets

NDC 41250-848-01

Meijer®

Compare to Maximum Strength Mucinex® FAST-MAX® DAY TIME Severe Congestion & Cough active ingredients* Daytime **severe cough & congestion** Dextromethorphan HBr 10 mg Guaifenesin 200 mg Phenylephrine HCl 5 mg Cough Suppressant Expectorant Nasal Decongestant MAXIMUM STRENGTH

Meijer®

Compare to Maximum Strength Mucinex® FAST-MAX® NIGHT TIME Cold & Flu active ingredients* Nighttime **cold & flu** **Acetaminophen 325 mg** Diphenhydramine HCl 12.5 mg Phenylephrine HCl 5 mg Pain Reliever/Fever Reducer Antihistamine/Cough Suppressant Nasal Decongestant MAXIMUM STRENGTH

- Relieves Aches, Fever & Sore Throat
- Relieves Nasal Congestion,

- Controls Cough,
- Relieves Nasal & Chest Congestion
- Thins & Loosens Mucus

20 Caplets
Actual Size

Runny nose
& Sneezing • Controls Cough

10 Caplets
Actual Size

*This product is not manufactured or distributed by RB Health (US) LLC, owner of the registered trademark Maximum Strength Mucinex® FAST-MAX® Day Time Severe Congestion & Cough and Night Time Cold & Flu.
50844 REV1021B64869401

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DISTRIBUTION, INC.
GRAND RAPIDS, MI 49544
www.meijer.com**

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

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

meijer

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

COMBO PACK

Total 30 Caplets

NDC 41250-848-01

Compare to Maximum Strength Mucinex® FAST-MAX® DAY TIME Severe Congestion & Cough active ingredients*

Daytime severe cough & congestion

Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Cough Suppressant
Expectorant
Nasal Decongestant

MAXIMUM STRENGTH

- Controls Cough
- Relieves Nasal & Chest Congestion
- Thins & Loosens Mucus

20

Caplets

Actual Size

Compare to Maximum Strength Mucinex® FAST-MAX® NIGHT TIME Cold & Flu active ingredients*

Nighttime cold & flu

Acetaminophen 325 mg
Diphenhydramine HCl 12.5 mg
Phenylephrine HCl 5 mg

Pain Reliever/Fever Reducer
Antihistamine/Cough Suppressant
Nasal Decongestant

MAXIMUM STRENGTH

- Relieves Aches, Fever & Sore Throat
- Relieves Nasal Congestion, Runny Nose & Sneezing
- Controls Cough

10

Caplets

Actual Size

C-1214-648694-011
REV1021B64869401

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REV1021B64869401

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GRAND RAPIDS, MI 49544
www.meijer.com

PARENTS: Look for the tamper-evident seal on the blister pack.



NO VARNISH OR PRINTING LOT # & EXP. DATE AREA

FID 4338254



Drug Facts KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active ingredients (in each caplet) Purpose (Daytime Severe Congestion & Cough)

Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Active ingredients (in each caplet) Purpose (Nighttime Cold & Flu)

Acetaminophen 325 mg	Pain reliever/fever reducer
Diphenhydramine HCl 12.5 mg	Antihistamine/cough suppressant
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Uses (Daytime only)

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- temporarily relieves these common cold and flu symptoms:
 - headache
 - sore throat
 - nasal congestion
 - runny nose and sneezing
 - cough
 - minor aches and pains
 - temporarily reduces fever
 - controls cough to help you get to sleep

PEEL CORNER TO READ COMPLETE DRUG FACTS

Drug Facts (continued)

Warnings

(Nighttime only)

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- with other drugs containing acetaminophen
- more than 4,000 mg of acetaminophen in 24 hours
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- hives
- skin redness
- itching
- swelling of the face, lips, tongue, or throat
- difficulty breathing
- fever
- skin rash
- skin redness

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

- 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.
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- if you have ever had an allergic reaction to this product or any of its ingredients (Nighttime only)
- with any other product containing diphenhydramine, even one used on skin (Nighttime only)

Ask a doctor before use if you have

- heart disease
- diabetes
- thyroid disease
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- high blood pressure

Drug Facts (continued)

- difficulty in urination due to enlargement of the prostate gland
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis (Nighttime only)
- glaucoma (Nighttime only)
- liver disease (Nighttime only)

Ask a doctor or pharmacist before use if you are (Nighttime only)

- 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 (Nighttime only)
- alcohol, sedatives, and tranquilizers may increase drowsiness (Nighttime only)
- use caution when driving a motor vehicle or operating machinery (Nighttime only)
- avoid alcoholic beverages (Nighttime only)
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Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
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- new symptoms occur (Nighttime only)
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- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

Drug Facts (continued)

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. Do not take DAYTIME and NIGHTTIME products at the same time.

Directions

- do not take more than directed
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Other information

- 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)
- use by expiration date on package

Inactive ingredients (Daytime only) corn starch, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, poly sorbate 80, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Inactive ingredients (Nighttime only) corn starch, croscarmellose sodium, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, iron oxide yellow, magnesium stearate, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium bicarbonate, stearic acid, talc, titanium dioxide

Drug Facts (continued)

Questions or comments? 1-800-426-9391

Do not take the Daytime and Nighttime caplets at the same time.

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Meijer 44-648694

SEVERE COUGH AND CONGESTION AND COLD AND FLU DAYTIME, NIGHTTIME

acetaminophen, dextromethorphan hbr, diphenhydramine hcl, guaifenesin, phenylephrine hcl kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:41250-848

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-848-01	1 in 1 CARTON; Type 0: Not a Combination Product	07/01/2017	01/29/2026

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	20
Part 2	1 BLISTER PACK	10

Part 1 of 2

SEVERE COUGH AND CONGESTION DAYTIME

dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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)	
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
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	red (Maroon)	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	44;648
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		10 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	07/20/2015	

Part 2 of 2

COLD AND FLU NIGHTTIME

acetaminophen. diphenhydramine hcl, phenylephrine hcl tablet, film coated

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	44;694
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		10 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	07/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/01/2017	01/29/2026

Labeler - Meijer Distribution Inc (006959555)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(41250-848) , pack(41250-848)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(41250-848)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(41250-848)

Revised: 3/2024

Meijer Distribution Inc