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

Meijer 44-648694

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
  - the impulse to cough to help you get to sleep
- 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

Liver warning *(Nighttime only)*: 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 *(Nighttime only)*: 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 *(Nighttime only)*: 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 product containing diphenhydramine, even one used on skin ***(Nighttime only)***
- 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

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 tranquilizers

When using this product
- **do not exceed recommended dosage**
- marked drowsiness may occur ***(Nighttime only)***
- 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)***

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 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

- **each caplet contains:** sodium 3 mg***(Daytime only)***
- **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
30 CAPLETS TOTAL

NDC 41250-848-95

Meijer® Maximum Strength **Daytime Severe Congestion & Cough** Dextromethorphan HBr 10 mg Guaifenesin 200 mg Phenylephrine HCl 5 mg Cough Suppressant Expectorant Nasal Decongestant • Controls Cough • Relieves Nasal & Chest Congestion • Thins & Loosens Mucus **20** Caplets	Maximum Strength **Nighttime Cold & Flu Acetaminophen 325 mg** Diphenhydramine HCl 12.5 mg Phenylephrine HCl 5 mg Pain Reliever/Fever Reducer Antihistamine/Cough Suppressant Nasal Decongestant • Relieves Aches, Fever & Sore Throat • Relieves Nasal Congestion, Runny nose & Sneezing • Controls Cough **10** Caplets

Actual Size Actual Size

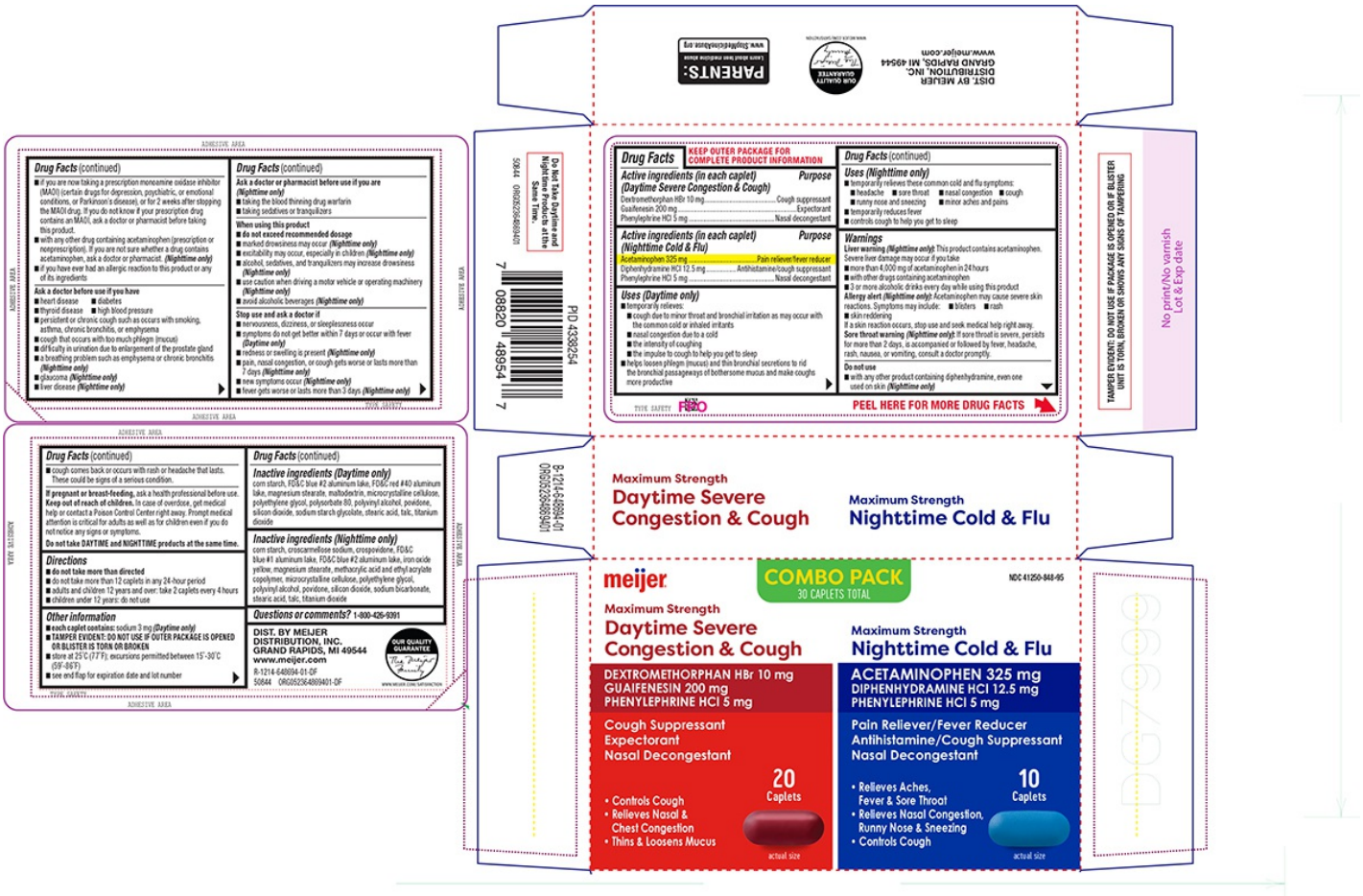
50844 ORG052364869401

Do Not Take Daytime and Nighttime Products at the Same Time

DIST. BY MEIJER 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 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:41250-848-95	1 in 1 CARTON; Type 0: Not a Combination Product	01/03/2024	

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	
Item Code (Source)	NDC:41250-591
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: 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	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	NDC:41250-591-03	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	01/03/2024	

Part 2 of 2

COLD AND FLU NIGHTTIME

acetaminophen. diphenhydramine hcl, phenylephrine hcl tablet, film coated

Product Information

Item Code (Source)	NDC:41250-592
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)	
CROSPOVIDONE, 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: 3WQ0SDW1A)	
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	NDC:41250-592-03	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	01/03/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/03/2024	

Labeler - Meijer Distribution Inc (006959555)

Establishment

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

Establishment

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

Establishment

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

Revised: 1/2024 Meijer Distribution Inc