**COLD AND FLU SEVERE DAYTIME, NIGHTTIME- acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, guaifenesin, phenylephrine hcl**
**Meijer Distribution, Inc.**

---

**Meijer 44-503C473A-08**

### *Active ingredients (in each caplet) (Daytime Cold & Flu Severe)*

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

### *Purpose*

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

### *Active ingredients (in each caplet) (Nighttime Cold & Flu Severe)*

Acetaminophen 325 mg
Chlorpheniramine maleate 2 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

### *Purpose*

Pain reliever/fever reducer
Antihistamine
Cough suppressant
Nasal decongestant

### *Uses*

- temporarily relieves these common cold and flu symptoms:
  - cough
  - sore throat
  - headache
  - nasal congestion
  - minor aches and pains
  - sinus congestion and pressure
  - sneezing and runny nose ***(Nighttime only)***
- helps clear nasal passages

- relieves cough to help you sleep
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive ***(Daytime only)***
- 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**

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

**Ask a doctor or pharmacist before use if you are**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers ***(Nighttime only)***

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

**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.

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

***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 (Daytime only)***

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

***Inactive ingredients (Nighttime only)***

corn starch, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, flavor, magnesium stearate, 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***

**meijer®**

NDC 79481-5034-8

**COMBO PACK**
**24 CAPLETS TOTAL**

| | |
|---|---|
| COMPARE TO TYLENOL®<br>COLD + FLU SEVERE DAY<br>ACTIVE INGREDIENTS*<br>**Daytime**<br>**COLD & FLU SEVERE**<br>**ACETAMINOPHEN**<br>**DEXTROMETHORPHAN HBr**<br>**GUAIFENESIN**<br>**PHENYLEPHRINE HCl**<br>**Pain Reliever/Fever Reducer**<br>**Cough Suppressant**<br>**Expectorant**<br>**Nasal Decongestant**<br>Fever, Headache,<br>Sore Throat,<br>Nasal Congestion,<br>Cough, Mucus,<br>Chest Congestion<br>Actual Size<br>**16**<br>DAYTIME<br>CAPLETS | COMPARE TO TYLENOL®<br>COLD + FLU SEVERE NIGHT<br>ACTIVE INGREDIENTS*<br>**Nighttime**<br>**COLD & FLU SEVERE**<br>**ACETAMINOPHEN**<br>**CHLORPHENIRAMINE MALEATE**<br>**DEXTROMETHORPHAN HBr**<br>**PHENYLEPHRINE HCl**<br>**Pain Reliever/Fever Reducer**<br>**Antihistamine**<br>**Cough Suppressant**<br>**Nasal Decongestant**<br>Fever, Headache,<br>Sore Throat,<br>Runny Nose, Cough,<br>Nasal Congestion<br>Actual Size<br>**8**<br>NIGHTTIME<br>CAPLETS |

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER**

**UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

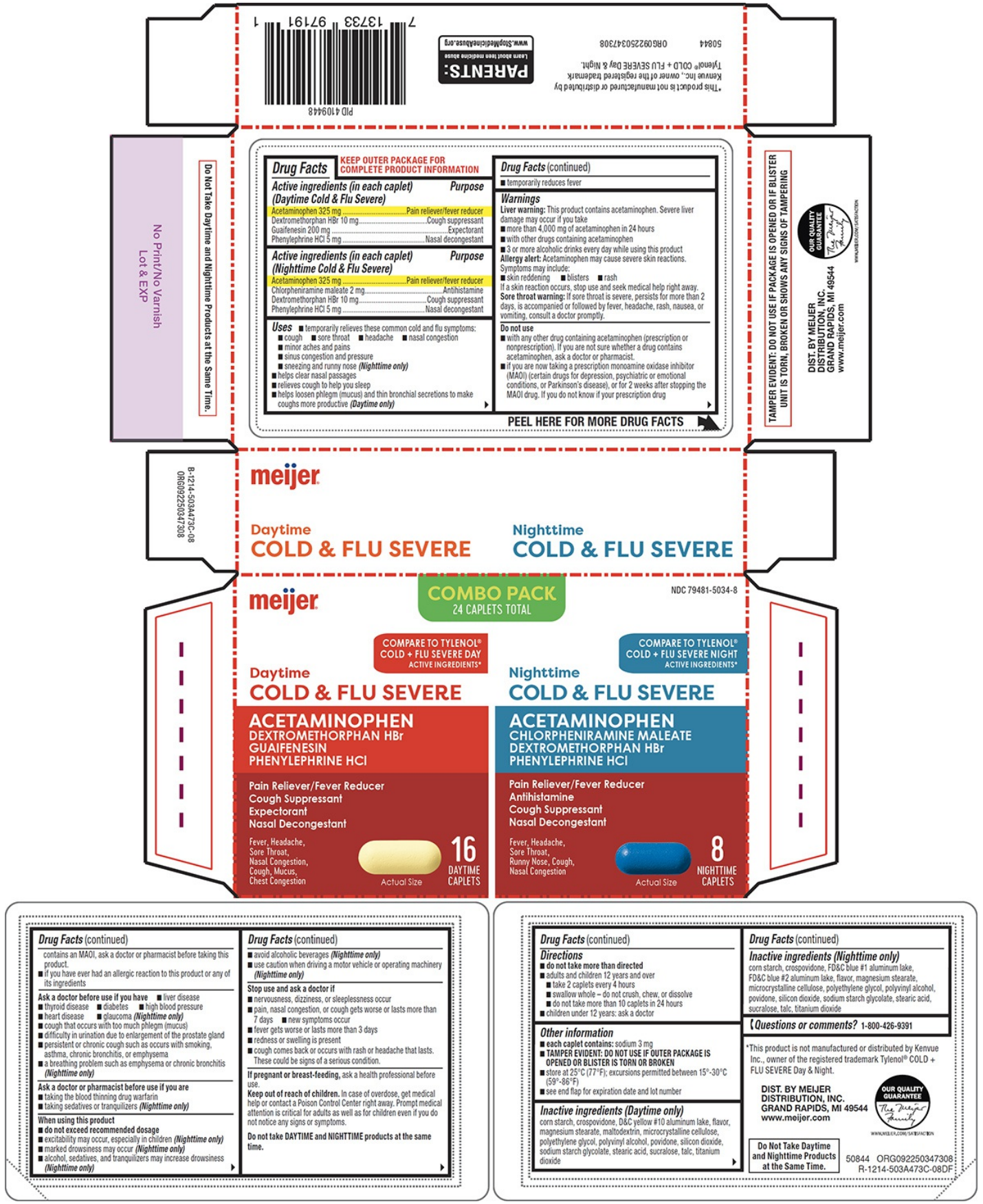
**Do Not Take Daytime and Nighttime Products at the Same Time.**

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

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

*This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark Tylenol® COLD + FLU SEVERE Day & Night.

50844 ORG092250347308




**Meijer 44-503A473C-08**

# COLD AND FLU SEVERE DAYTIME, NIGHTTIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, guaifenesin, phenylephrine hcl

kit

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:79481-5034 |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:79481-5034-8 | 2 in 1 CARTON | 11/08/2024 | |
| **1** | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

| Quantity of Parts | | |
|---|---|---|
| **Part #** | **Package Quantity** | **Total Product Quantity** |
| **Part 1** | | 8 |
| **Part 2** | | 4 |

## Part 1 of 2

## COLD AND FLU SEVERE DAYTIME

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

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:79481-9503 |
| **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, 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: 3WQ0SDW1A) | |
| **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** | | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M012 | 11/08/2024 | |

## Part 2 of 2

## COLD AND FLU SEVERE NIGHTTIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl tablet, film coated

### Product Information

| | |
|---|---|
| **Item Code (Source)** | NDC:79481-9473 |
| **Route of Administration** | ORAL |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| **CHLORPHENIRAMINE MALEATE** (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U) | CHLORPHENIRAMINE MALEATE | 2 mg |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **CROSPOVIDONE, UNSPECIFIED** (UNII: 2S7830E561) | |
| **FD&C BLUE NO. 1 ALUMINUM LAKE** (UNII: J9EQA3S2JM) | |
| **FD&C BLUE NO. 2 ALUMINUM LAKE** (UNII: 4AQJ3LG584) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **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** | blue | **Score** | no score |
| **Shape** | OVAL | **Size** | 17mm |
| **Flavor** | MENTHOL | **Imprint Code** | 44;473 |
| **Contains** | | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M012 | 11/08/2024 | |


## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M012 | 11/08/2024 | |


## Labeler - Meijer Distribution, Inc. (006959555)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 832867837 | manufacture(79481-5034) , pack(79481-5034) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|

| | | | |
|---|---|---|---|
| LNK International, Inc. | | 832867894 | manufacture(79481-5034) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 117025878 | manufacture(79481-5034) |

Revised: 11/2024

Meijer Distribution, Inc.