

**COLD AND FLU DAYTIME SEVERE- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated  
Meijer Distribution Inc**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Meijer 44-640**

***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 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***

- **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, 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***

**meijer®**

**NDC 41250-643-08**

**Compare to  
Vicks® DayQuil® VapoCOOL®  
SEVERE COLD & FLU +  
CONGESTION  
active ingredients\***

**MAXIMUM STRENGTH  
daytime**

**severe  
cold & flu**

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

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

24 Caplets

Actual  
Size

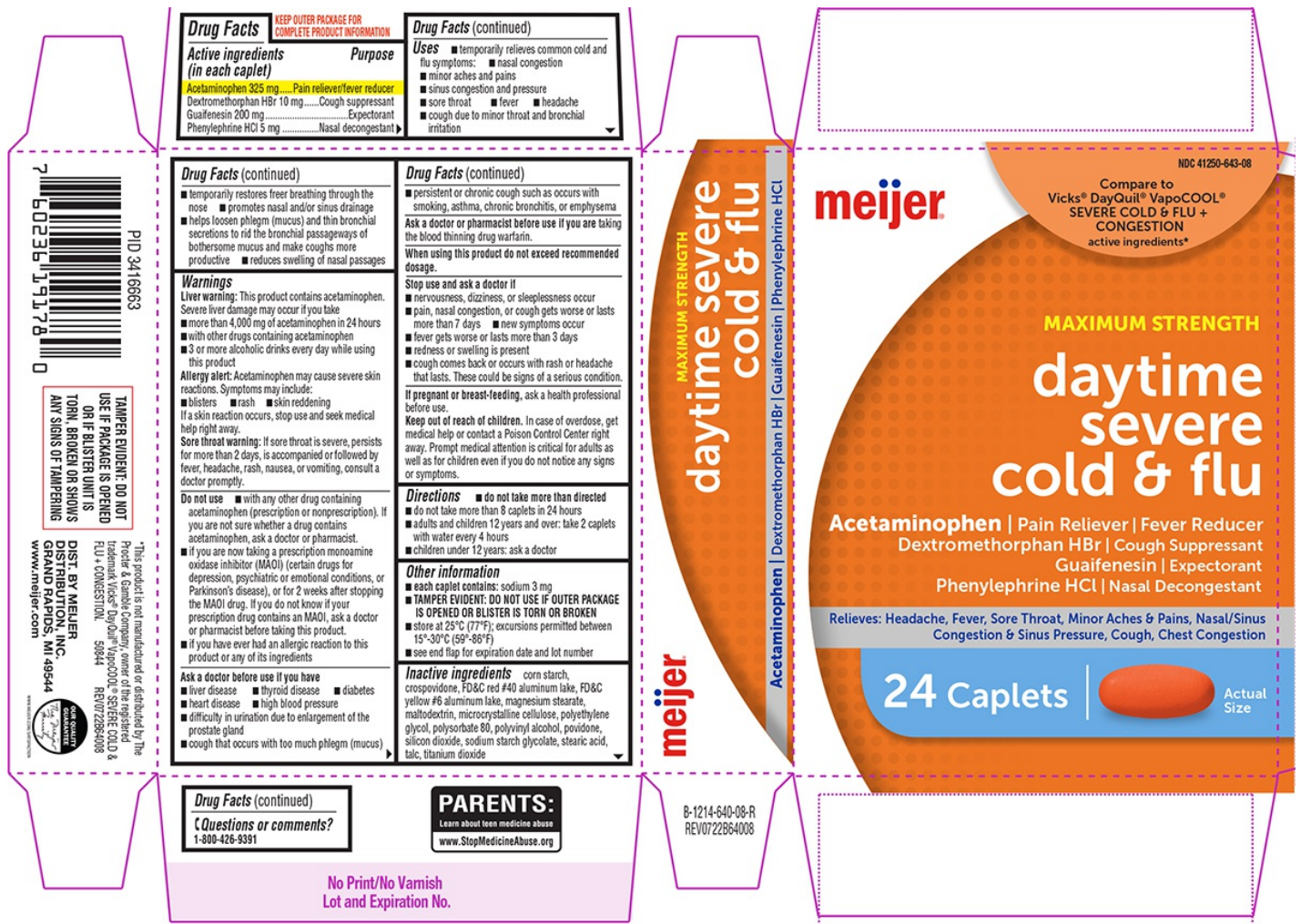
**TAMPER EVIDENT: DO NOT  
USE IF PACKAGE IS OPENED  
OR IF BLISTER UNIT IS  
TORN, BROKEN OR SHOWS  
ANY SIGNS OF TAMPERING**

\*This product is not manufactured or distributed by The  
Procter & Gamble Company, owner of the registered  
trademark Vicks® DayQuil® VapoCOOL® SEVERE COLD &  
FLU + CONGESTION. 50844 REV0722B64008

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GRAND RAPIDS, MI 49544  
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OUR QUALITY  
GUARANTEE  
*The Meijer  
Family*



meijer 44-640

## COLD AND FLU DAYTIME SEVERE

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

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-643
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg	
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	
Inactive Ingredients			
Ingredient Name	Strength		

<b>STARCH, CORN</b> (UNII: O8232NY3SJ)
<b>CROSPVIDONE</b> (UNII: 2S7830E561)
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>TALC</b> (UNII: 7SEV7J4R1U)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	44;640
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-643-08	2 in 1 CARTON	05/08/2020	
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 final	part341	05/08/2020	

**Labeler** - Meijer Distribution Inc (006959555)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(41250-643) , pack(41250-643)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(41250-643)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(41250-643)

Revised: 1/2023

Meijer Distribution Inc