

**NITETIME COLD AND FLU- acetaminophen, dextromethorphan hbr,
doxylamine succinate solution
Meijer Distribution Inc**

Meijer Distribution, Inc. NiteTime Cold & Flu Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

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
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough as occurs with smoking, asthma, or emphysema
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

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

When using this product

- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- pain 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. Overdose warning:

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- take only as directed – see Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- **each 30 mL contains:** sodium 39 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

alcohol, anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions?

1-800-719-9260

Package/Label Principal Display Panel

meijer®

MAXIMUM STRENGTH

NiteTime Cold & Flu

Acetaminophen (Pain Reliever/Fever Reducer)

Dextromethorphan HBr (Cough Suppressant) | Doxylamine Succinate (Antihistamine)

COMPARE TO VICKS® NYQUIL® COLD & FLU ACTIVE INGREDIENTS

RELIEVES: ACHES, PAIN, FEVER, SORE THROAT, SNEEZING, RUNNY NOSE, COUGH

CHERRY FLAVOR

ALCOHOL 10%

Multi-Symptom Relief

12 FL OZ (355 mL)



The image shows a label for Meijer NiteTime Cold & Flu. The label is primarily white and blue. At the top, the Meijer logo is in red. Below it, the text 'MAXIMUM STRENGTH' is in blue, followed by 'NiteTime Cold & Flu' in large blue letters. To the right of this text, 'NDC 41250-459-40' is printed vertically. The ingredients are listed: Acetaminophen (Pain Reliever/Fever Reducer), Dextromethorphan HBr (Cough Suppressant), and Doxylamine Succinate (Antihistamine). A blue box contains the text 'COMPARE TO VICKS® NYQUIL® COLD & FLU ACTIVE INGREDIENTS*'. Below this, another blue box lists symptoms: 'RELIEVES: ACHES, PAIN, FEVER, SORE THROAT, SNEEZING, RUNNY NOSE, COUGH'. A red banner with 'CHERRY FLAVOR' and an image of two cherries is present. The label also states 'ALCOHOL 10%' and 'Multi-Symptom Relief'. At the bottom, it says '12 FL OZ (355 mL)' and has a small white box with the number '45940 6E F7'.

meijer.

MAXIMUM STRENGTH

**NiteTime
Cold & Flu**

NDC 41250-459-40

Acetaminophen
(Pain Reliever/Fever Reducer)
Dextromethorphan HBr (Cough
Suppressant) | Doxylamine
Succinate (Antihistamine)

COMPARE TO VICKS® NYQUIL®
COLD & FLU ACTIVE INGREDIENTS*

RELIEVES: ACHES, PAIN, FEVER,
SORE THROAT, SNEEZING,
RUNNY NOSE, COUGH

CHERRY
FLAVOR

ALCOHOL 10%
Multi-Symptom Relief

12 FL OZ (355 mL)

45940 6E F7

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

**DO NOT USE IF PRINTED NECKBAND
IS BROKEN OR MISSING**

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

PID 415275

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13733 64842
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Drug Facts

Active ingredients (in each 30 mL)	Purpose
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 30 mg	Cough suppressant
Doxylamine succinate 12.5 mg	Antihistamine

Uses temporarily relieves common cold/flu symptoms:
 ■ cough due to minor throat and bronchial irritation
 ■ sore throat ■ headache ■ minor aches and pains
 ■ fever ■ runny nose and sneezing

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.

PEEL BACK AT CORNER FOR MORE INFORMATION

: 45940 6E 82

Drug Facts
(continued)

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.
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 ■ liver disease ■ glaucoma
 ■ cough that occurs with too much phlegm (mucus) ■ a breathing problem such as emphysema or chronic bronchitis ■ trouble urinating due to an enlarged prostate gland ■ persistent or chronic cough as occurs with smoking, asthma, or emphysema
 ■ a sodium-restricted diet

Ask a doctor or pharmacist before use if you are ■ taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin

ADHESIVE AREA
NO COATING • NO VARNISH • NO TYPE

Drug Facts
(continued)

When using this product ■ excitability may occur, especially in children ■ marked drowsiness may occur ■ avoid alcoholic drinks
 ■ be careful when driving a motor vehicle or operating machinery ■ alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if ■ pain 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.

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Directions	
■ take only as directed – see Overdose warning	■ only use the dose cup provided
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Other information ■ each 30 mL contains: sodium 39 mg ■ store at 20-25°C (68-77°F)

Inactive ingredients alcohol, anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions? 1-800-719-9260

*This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademarks Vicks® and MyQuil®.

ADHESIVE AREA
NO COATING • NO VARNISH • NO TYPE

NITETIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-459
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength

ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	

Product Characteristics

Color	RED (Clear/Dark Red)	Score	
Shape		Size	
Flavor	CHERRY (Menthol Aroma)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-459-38	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/21/2011	02/12/2014
2	NDC:41250-459-43	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2011	10/10/2018
3	NDC:41250-459-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/29/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/09/2011	

Labeler - Meijer Distribution Inc (006959555)