### DAYTIME NITETIME COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl 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 Distribution, Inc. DayTime NiteTime Cold & Flu Drug Facts

#### Nighttime Cold & Flu 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
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- 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 or comments?

1-800-719-9260

#### Daytime Cold & Flu Active ingredients (in each 15 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

#### **Purpose**

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

#### Uses

• temporarily relieves common cold/flu symptoms:

- nasal congestion
- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever

#### Warnings

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

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 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
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

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

taking the blood thinning drug warfarin

#### When using this product

#### do not use more than directed

#### Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- 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 4 hrs
children 6 to under 12 yrs	15 mL every 4 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

#### Other information

- each 15 mL contains: sodium 7 mg
- store at 20-25°C (68-77°F)

#### **Inactive ingredients**

butylated hydroxyanisole, edetate disodium, FD&C yellow no. 6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

#### Questions or comments?

1-800-719-9260

#### **Principal Display Panel**

**COMBO PACK** 

Compare to Vicks® DayQuil® active ingredients

**NON-DROWSY** 

MAXIMUM STRENGTH

daytime cold & flu

Acetaminophen | Pain Reliever | Fever Reducer

Dextromethorphan HBr | Cough Suppressant

Phenylephrine HCl | Nasal Decongestant

Powerful Non-Drowsy Relief

Alcohol Free

Antihistamine Free

12 FL OZ (355 mL)

Compare to Vicks® NyQuil® active ingredients

MAXIMUM STRENGTH

nitetime cold & flu

Acetaminophen | Pain Reliever | Fever Reducer

Dextromethorphan HBr | Cough Suppressant

Doxylamine Succinate | Antihistamine

Powerful Nighttime Relief

Cherry Flavor

**ALCOHOL 10%** 

12 FL OZ (355 mL)



\*These products are not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademarks Vicks® NyQuil® and DayQuil®.

Inactive ingredients butylated hydroxyanisole, edetate discollum, FD&C yellow n.o. 6, flavor, glycerin, merithol, mondoasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, suroose, xanthan gum

uestions or comments?1-800-719-9260

DO NOT USE IF PRINTED NE CKBAND IS BROKEN OR MISSING

Drug Facts (continued)

meijer

**COMBO PACK** 

NDC 41250-733-02

Compare to

Vicks® NyQuil® active ingredients\*

**MAXIMUM STRENGTH** 

nitetime

cold & fl

Acetaminophen | Pain Reliever | Fever Reducer

Dextromethorphan HBr | Cough Suppressant

Doxylamine Succinate | Antihistamine

**Powerful Nighttime Relief** 

Cherry Flavor

12 FL 0Z (355 mL)

**ALCOHOL 10%** 





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

Questions or comments? 1-800-719-9260

Inactive ingredients alcohol, anhydrous citricacid, FD&C blue no. 1, FD&C ed no. 40, flavor, high fuddes com synup, polystitylare glycol, propylene glycol, purified water, saccharin's collum, sodium citrate Drug Facts (continued)

meijer

active ingredients\*

MAXIMUM STRENGTH

Vicks® DayQuil®

# daytime

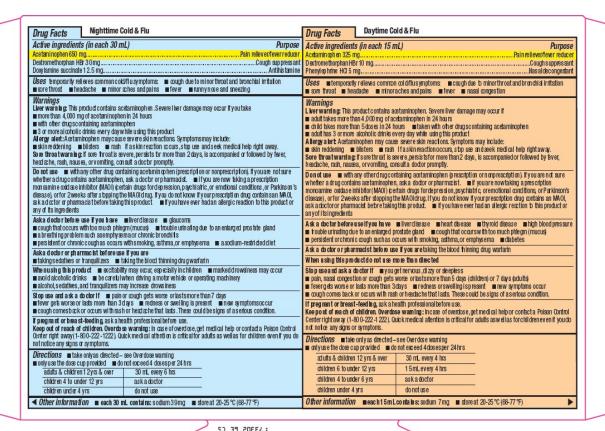
Acetaminophen | Pain Reliever | Fever Reducer Dextromethorphan HBr | Cough Suppressant Phenylephrine HCl | Nasal Decongestant

Powerful Non-Drowsy Relief

**Alcohol Free** Antihistamine Free

12 FL 0Z (355 mL)

CODE AREA







#### DAYTIME NITETIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41250-733

#### **Packaging**

	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:41250-733-02	1 in 1 CARTON; Type 0: Not a Combination Product	10/24/2012	

#### **Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	355 mL
Part 2	1 BOTTLE	355 mL

#### Part 1 of 2

#### NITETIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

#### **Product Information**

Item Code (Source) NDC:41250-459

Route of Administration ORAL

#### **Active Ingredient/Active Moiety Basis of Strength Ingredient Name** Strength 650 mg ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D) ACETAMINOPHEN in 30 mL **DEXTRO METHO RPHAN HYDRO BRO MIDE** (UNII: 9 D2RTI9 KYH) DEXTROMETHORPHAN 30 mg (DEXTROMETHORPHAN - UNII:7355X3ROTS) HYDROBROMIDE in $30\ mL$ DO XYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DO XYLAMINE -12.5 mg DOXYLAMINE SUCCINATE UNII:95QB77JKPL) in 30 mL

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
ANHYDRO US 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 (UNII: 3WJQ0SDW1A)		
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)		
WATER (UNII: 059QF0KO0R)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		

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

ı	Pa	ckaging			
ı	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1 N	IDC:41250-459-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product		

	<b>Marketing Infor</b>	mation		
ı	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

#### Part 2 of 2

#### DAYTIME COLD AND FLU NON DROWSY

acetaminophen, dextromethorphan hbr, phenylephrine hcl solution

#### **Product Information**

Item Code (Source) NDC:41250-656

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg in 15 mL	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL	

Inactive Ingredients		
Ingredient Name	Strength	
BUTYLATED HYDRO XYANISOLE (UNII: REK4960K2U)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GLYCERIN (UNII: PDC6A3C0OX)		
MENTHOL (UNII: L7T10EIP3A)		
SO DIUM PHO SPHATE, MO NO BASIC (UNII: 3980 JIH2SW)		
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		
SUCROSE (UNII: C151H8M554)		
XANTHAN GUM (UNII: TTV12P4NEE)		

# Product Characteristics Color ORANGE (clear) Score Shape Size Flavor MENTHOL (with fruit) Imprint Code Contains

#### **Packaging**

# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1 NDC:41250-656-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product			
Marketing Inf	ormation			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	09/15/1989		
Marketing Inf	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	10/24/2012		

## Labeler - Meijer Distribution Inc (006959555)

Revised: 2/2019 Meijer Distribution Inc