NITETIME DAYTIME 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.

Meijer Distribution, Inc. NiteTime DayTime Cold & Flu Drug Facts

Nighttime Severe Cold & Flu Active ingredients (in each 30 mL)

Acetaminophen 650 mg
Dextromethorphan HBr 20 mg
Doxylamine succinate 12.5 mg
Phenylephrine HCl 10 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Antihistamine
Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion and pressure
- minor aches and pains
- headache
- fever
- sore throat
- runny nose and sneezing
- cough due to minor throat and bronchial irritation
- cough to help you sleep
- reduces swelling of nasal passages
- promotes nasal and/or sinus drainage
- temporarily restores freer breathing through the nose

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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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 such 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

- do not use more than directed
- 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

- you get nervous, dizzy or sleepless
- 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.

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 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- each 30 mL contains: sodium 41 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose, xanthan gum

Questions or comments?

1-800-719-9260

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

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCI 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

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

- 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
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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, 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 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 care 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 6 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

butylated hydroxyanisole, edetate disodium, FD&C yellow #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 - Nighttime

DAYTIME & NITETIME COMBO PACK

Compare to Vicks $^{\circledR}$ NyQuil $^{\circledR}$ Severe and DayQuil $^{\circledR}$ Severe active ingredients meijer $_{\circledR}$

Compare to Vicks® DayQuil® Severe active ingredients

meijer_® MAXIMUM STRENGTH **NON-DROWSY** daytime cold & flu Acetaminophen Pain Reliever | Fever Reducer Dextromethorphan HBr Cough Suppressant Guaifenesin | Expectorant Phenylephrine HCl Nasal Decongestant **SEVERE** Alcohol Free Antihistamine Free Compare to Vicks® NyQuil® Severe active ingredients meijer_® MAXIMUM STRENGTH nitetime cold & flu Acetaminophen Pain Reliever | Fever Reducer Dextromethorphan HBr Cough Suppressant Doxylamine Succinate **Antihistamine** Phenylephrine HCI Nasal Decongestant **SEVERE** Mixed Berry Flavor Sugar Free | Alcohol Free

Sugar Free | Alcohol Free Multi-Symptom Relief 2 - 12 FL OZ (355 mL) BOTTLES TOTAL 24 FL OZ (1.5 pt) (710 mL)



59702 6E C5



Nighttime Severe Cold & Flu

Daytime Severe Cold & Flu

Drug Facts

Active ingredients (in each 30 mL) Purpose Deotromethorphan H Br 20 mg..... Dooylamine succinate 12.5 mg.... Phenylephrine HCl 10 mg.... ...Cou gh suppressantArtihista nine ...Nasai decongestant

- Uses temporarily releves common c eld/flu symptoms:

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Keep out of reach of children, Overdose warring: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Oxick medical affection is critical for dutus as well as the children even if you do not notice any signs or symptoms.

Directions

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Other information

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Questions or comments? 1-800-719-9260

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- If you have ever had an allergic reaction to this product or any of its ingredients

- Ask a doctor before use if you have

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Ask a doctor or pharmacist before use if you are taking the blood thinning drug wartarin 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
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- m take only as directed see 0 verdiose warming m only use the dose cup provided m 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 yra ask a doctor children under 4 yra donot use

- Other information
- each 15 mL contains: sodium 6 mg store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients tutytaled hydroxyariscle, edetale disodum, FDSC yelow #8, favor, glycetin, menhol, monotosic sodium phosphate, polyethylene glycxi, propylene glycxi, punted water, saccharin sodium, sucrose, xanthan gun

Questions or comments? 1-800-719-9260

meijer

Compare to Vicks® DayQuil® Severe

MAXIMUM NON-DROWS

daytime cold & flu

SEVERE

Multi-Symptom Relief

Alcohol Free Antihistamine Free



www.StopMedicineAbuse.org



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NITETIME DAYTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41250-597

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:41250-597- 02	1 in 1 KIT; Type 0: Not a Combination Product	12/30/2013	

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, phenylephrine hcl solution

Product Information

Item Code (Source)	NDC:41250-763
Route of Administration	ORAL

Active Ingredient/Active Moiety Basis of Strength Ingredient Name Strength 650 mg ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN in 30 mL **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) **DEXTROMETHORPHAN** 20 mg (DEXTROMETHORPHAN - UNII:7355X3ROTS) **HYDROBROMIDE** in 30 mL DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE -12.5 mg DOXYLAMINE SUCCINATE in 30 mL UNII:95QB77JKPL) PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -PHENYLEPHRINE 10 mg

HYDROCHLORIDE

in 30 mL

Inactive Ingredients

UNII:1WS297W6MV)

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	RED (clear, dark)	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:41250-763-	355 mL in 1 BOTTLE; 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	12/11/2013	

Part 2 of 2

DAYTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

Product Information	
Item Code (Source)	NDC:41250-603
Route of Administration	ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg in 15 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL	

Inactive Ingredients	
Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	ORANGE (clear)	Score	
Shape		Size	
Flavor	FRUIT, MENTHOL	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-603- 40	355 mL in 1 BOTTLE; 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	12/11/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/30/2013	

Labeler - Meijer Distribution Inc (006959555)

Revised: 9/2022 Meijer Distribution Inc