NITETIME COUGH DAYTIME COUGH- dextromethorphan hydrobromide, doxylamine succinate
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 Cough DayTime Cough Drug Facts

Nighttime Cough
Active ingredients (in each 30 mL)

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

Purpose

Cough suppressant

Antihistamine

Uses

temporarily relieves cold symptoms:

- cough due to minor throat and bronchial irritation
- runny nose and sneezing

Warnings

Do not use

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.

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

- excitability may occur, especially in children
- may cause marked drowsiness
- 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

cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign 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 (1-800-222-1222).

Directions

- take only as directed
- 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 32 mg
- store at 20-25°C (68°-77°F)

Inactive ingredients

alcohol, anhydrous citric acid, FD&C blue #1, FD&C red #40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions or comments?

1-800-719-9260

Daytime Cough
Active ingredient (in each 15 mL)

Dextromethorphan HBr 15 mg

Purpose

Cough suppressant

Uses

temporarily relieves cough due to minor throat and bronchial irritation associated with a cold

Warnings

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Directions

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adults & children 12 yrs & over	30 mL every 6-8 hrs
children 6 to under 12 yrs	15 mL every 6-8 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- each 15 mL contains: sodium 13 mg
- store at 20-25°C (68-77F)
- does not meet USP requirements for light resistant packaging

Inactive ingredients

anhydrous citric acid, D&C yellow #10, FD&C yellow #6, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions or comments?

1-800-719-9260

Principal Display Panel – NiteTime Cough

COMBO PACK

Compare to Vicks® NyQuil® Cough active ingredients

nitetime cough

Dextromethorphan HBr

Cough Suppressant

Doxylamine Succinate | Antihistamine

All Night Cough Relief

Cherry Flavor

ALCOHOL 10%

Relieves: Cough, Sneezing, Runny Nose

12 FL OZ (355 mL)

Principal Display Panel – DayTime Cough

COMBO PACK

Compare to Vicks® DayQuil® Cough active ingredient

NON-DROWSY

daytime cough

Dextromethorphan HBr

Cough Suppressant

All Day Cough Relief

Citrus Blend Flavor

Alcohol Free

Antihistamine Free

Powerful Cough Relief for up to 8 hours

12 FL OZ (355 mL)

Drug Facts Nighttime Cough

Active Ingredients (In each 30 mL) ***Purpose***
Dextromethorphan HBr 30 mg ..... Cough suppressant
Doxylamine succinate 12.5 mg ..... Antihistamine

Uses temporarily relieves cold symptoms:
- runny nose and sneezing
- cough due to minor throat and bronchial irritation

Warnings

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Drug Facts Daytime Cough

Active Ingredient (In each 15 mL) ***Purpose***
Dextromethorphan HBr 15 mg ..... Cough suppressant

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Inactive Ingredients
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NITETIME COUGH DAYTIME COUGH

dextromethorphan hydrobromide, doxylamine succinate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-031

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-031-02	1 in 1 KIT; Type 0: Not a Combination Product	02/13/2013	

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 COUGH

dextromethorphan hydrobromide, doxylamine succinate solution

Product Information

Item Code (Source)	NDC:41250-668
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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: 3WQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics			
Color	RED (Dark Red)	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-668-40	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	03/03/2003	

Part 2 of 2

DAYTIME COUGH NON DROWSY

dextromethorphan hydrobromide solution

Product Information	
Item Code (Source)	NDC:41250-473
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	

Product Characteristics			
Color	ORANGE (light)	**Score**	
Shape		**Size**	
Flavor	CITRUS (blend)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-473-40	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	08/15/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/13/2013	

Labeler - Meijer Distribution Inc (006959555)

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