NITETIME DAYTIME SEVERE COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate, guaifenesin, phenylephrine hcl Kroger Company

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.

Kroger Co. DayTime NiteTime Severe 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?

1-800-632-6900

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

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/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
- 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, 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?

1-800-632-6900

Principal Display Panel

COMPARE TO the active ingredients of VICKS® DAYQUIL® SEVERE COLD & FLU See side panel NON-DROWSY DayTime Severe Cold & Flu Acetaminophen, Phenylephrine HCl, Dextromethorphan HBr, Guaifenesin Pain Reliever / Fever Reducer, Nasal Decongestant, Cough Suppressant, Expectorant MAXIMUM STRENGTH RELIEF Alcohol Free Antihistamine Free Our Pharmacists Recommend 12 FL OZ (354mL) COMPARE TO the active ingredients of VICKS® NYQUIL® SEVERE COLD & FLU See side panel NiteTime Severe Cold & Flu

Acetaminophen, Dextromethorphan HBr, Doxylamine Succinate, Phenylephrine HCl Pain Reliever, Fever Reducer, Nasal Decongestant, Cough Suppressant, Antihistamine MAXIMUM STRENGTH RELIEF Our Pharmacists Recommend 12 FL OZ (354mL)

Berry Flavor



Drug Facts Nighttime Severe Cold & Flu	Drug Facts Daytime Severe Cold & Flu
Active ingredients (in each 30 mL) Purpose	Active ingredients (in each 15 mL) Purpose
Acetaminophen 660 mgPain relievenfever reducer Dext methorphan HBr2 OmgCough suppressant Doxylamine succinate 12.5 mgArith stamine Prenvipedrine AICI 10 mgNational Statemine Prenvipedrine AICI 10 mgNational Statemine AICI 10 mgNATIONAL AICI 10 m	Acelamin grien 325 mg
Uses temporarily relieves common ciddifusymptoms: anal congestion situation and pressure minor aches and pains beadache fover sover throat "runny nose and snezing soughdue to minor throat and bronchial initiation sough to help you sleep reduces aveiling of nasi passages promotes nasia and/or sinus of rainage temporarily restores freer breating fittory the hose so	Uses emporarily relieves common coldifiu symptoms in as alcongestion in sinus congestion and pressure accuption due to minor throad and the origital infration is minor aches and pairs in beadade is ver size throat infratures swelling of nasal passages interroporarily restores freer breathing through the nose promotes masuland for sinus drainage in helps losen philogin (mucus) and thin broach also er dit not to full the
Warnings Liver waning:Thisproduct contains a cetaminophen. Severe liver damage may occur if you take more than 4,000 mg of a cetaminophen in 24 hours ■ with other drugs containing a cetaminophen ■ 3 or more a lacholic drinksevery day will e using this product Alter yai etc. A cetaminophen may cause severe skin reactions. Symptoms may include: ■ Skin redden ing ■ bitters ■ rash. If a skin readron occurs, stop use and sever medical help night away. Sore hroat wan ing: if sore throat is severe, perisds for more han 2 days, is a accompanied or followed by fever, headach; a rish, nause, or wonling, consult a doctor promp ty.	brinchial passageways of bothersome mucus and make coughs more productive Warming s Uver warming c This product contains actaminophen. Severe liker damage may occur if adult takes more than 4 000 mg of acetamin ophen in 24 hours while takes more than 5 doxes in 24 hours while warming actaminophen actaminophen adult tas 3 ormore alcoholic drinksevery day while using this product Alergy aint: Actaminophen may cause saver e skin reactions. Symptomsmay include:
Do not use with any other drug containing actaminophen (prescription or nonprescription). If you are not sure whether a drug con a line actaminophen, ask a doctor or pharmads. Wity an arenow takinga prescription nonamine oxfase in hindur (Mol) pertain dung for depression, poyr diatric, or matorianal conditions, or Parkinson side asa), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug con bins an MAOI, as k a doctor	busites in task in a summary of the through severe presistor more than 2 days, is accompanied or followed by ever, headache, rast, nausea, or vormiting, consult adodor promptly. Do notuse in with any dher drug containing a setaminophen (prescription or nonprescription). If you are not sure whether a drug-contains as elaminophen, ask a doctro or pharmacist is if you are not variang areas rotifor nonconting
pharmacist before taking hisprodud. If you have ever had an allergic reaction b thisprodud or any offs ingredients Aska doctor before as elfyou have in ther disease in heart disease in high blood pressure in tyroid disease indicates in glaucoma wough that occurs with how much phlergin (mucus) is a for stitting problem such as empty semiaor chronic bronchits in trouble unrating due to an entirged prostate ligand in prostentor	where a doug-contains are traininghent, as a doctor or prainters. If you are now rawing apressiption introvanine unidas inhibitor. (MAO) (certain fungs br depression, psychiatric, ornau prescription doug contains an MAO, ask a doctor or 2 weeksafters bepting the MAOI drug. If you do nd know if your prescription drug contains an MAO, ask a doctor pharmacist bebre taking his product. If you have ever trad an allering creaction biths product orany of this ingedients Aska doctor before use If you have. If you have ever trad an allering creaction biths product orany of this ingedients.
chronic cough such as occurs with smoking, as thma, or emphysema a sodium-restricted det Ask a doctor or pharmacisk before use if you are a taking sedatives or tranquilizers a taking he blood thinning drug war farin When using this product a do a dusem ore than a freeled excitability may occur, especially in children	Aska doctor bettere usen inyou have ■ nev use ase ■ nevat use ase ■ niyou use ase ■ materies ■ high blood pressare ■ trubie urinaling due to an enlarged prostale gland ■ cough that occurs with bo much philogin (muus) ■ presistent or chronic ough such asoccurs with moking, asthma, irromic tronchills, or emphysena Aska doctor or pharmacist before use if you are taking the blood thinning drug warfarin
marked drowsiness may occur ■ avoid alcoholic drinks ■ be careful when driving a rotor vehicle or operating machinery ■ alcohol; sedatives, and tranquilizers may increase drowsiness	When using this product do not use more than directed Stop use and ask a doctor If myouget narvous, dizzy or skeepless
Stop use and ask a doctor # myou get nervous, dizy or skepkes. ■pain, nasalcongestion, or cough gets worse or katsmore than 7 days mifever gets worse or kats more than 3 days. ■ redness or swelling is present. ■ new symptoms occur	n pain, nasal congestion or cough jeter worse or kests möre than 5 days (childrein) or 7 days (childrein) merver gets worse or kas more than 3 days in rechess or swelling is present in new symptoms occur accugh comes tack cor occurs with reshor heckliche that kast. These coud be signs of a serious condition.
cough comes back or occurs with rash or headache that las b. These could be signs of a serious condition. If pregnant or breast-leading, aska health professional before use. Keep out for each of child han. O end ose warning: In case of otend ose, get medical help or contrada Poison Dontra' Center right away (1-800-222-122). Outick medical attention is critical or adults as wellast orch lidreneven if you do not notice any disno structions.	T pregnant or breast-feed hg ask a health professional before use. He ep out of reach of children. Overdo se we ming in case of overdose, get medical h ep or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adult is as well as for children even if you do not not ce any agers or symptoms.
Directions ■take mlyas directed - see Overdose warming ■ only use the dose oup provided ■ do not exceed 4 doses per 2 4 hrs	Directions ■ take only asclinected - see Overdose warning ■ only use the dose cup provided ■ do not exceed 4 doses per 24 hrs adults & children 1 2 yrs & over 30 mL every 4 hrs
adults & children 12 yrs & over 30 mL every 4 hrs children 4 to under 12 yrs ask a dodor	children 6 to under 12 yrs 15 mL every 4 hrs children 4 to under 6 yrs ask a docbr
children under 4 yrs do notuse ∢ Other information ■ each 30 mL contains: sodium 41 mg ■ store at 20-25 °C (68-77 °F)	children un der 4 yrs do not use Other information ■each 15m L contains: sodium 6 mg ■ store at 20-25 °C (68-7 7°F). Do not refniger ab. ►
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NITETIME DAYTIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, guaifenesin, phenylephrine hcl kit

Product Information	n				
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:30142-597	
Packaging					
# Item Code	Package Description		Marketing Start Date	Marketing End Date	
1 NDC:30142-597-02	1 in 1 KIT; Type 0: Not a Combination	Product	09/24/2014		
Quantity of Parts					
Part # P	Package Quantity		Total Product Qu	iantity	
Part 1 1BOTTLE		354 mL			
Part 2 1 BOTTLE		354 mL			
Part 1 of 2					

NITETIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl solution

Product Information	
Item Code (Source)	NDC:30142-763
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTRO METHO RPHAN HYDRO BRO MIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHO RPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
DO XYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DO XYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISO DIUM (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 SO DIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8 M554)	
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

1 NDC:30142-763-40 354 mL in 1 BOTTLE; Type 0: Not a Combination Product

Marketing Info	rmation					
Marketing Category		on Number or Monograph Citation	Mar	keting Start Date	Marketii	ng End Date
OTC monograph final	part341	Summer of Monograph Chatton	08/13	-	Mai Ke ui	
o i o monographi imai	pure l'		00/10			
Part 2 of 2						
DAYTIME SE	VERE CO	LD AND FLU				
acetaminophen, dex	tromethorpha	n hbr, guaifenesin, phenylephrine l	hcl solı	ution		
	-					
Product Informat	ion					
Item Code (Source)	.1011	NDC:30142-603				
	•					
Route of Administra	tion	ORAL				
Active Ingredient	/Active Moi	etv				
		dient Name		Basis of Stre	ength	Strength
ACETAMINOPHEN (U)		D) (ACETAMINOPHEN - UNII:36209ITLS)D)	ACETAMINOPHEN	0	325 mg in 15 mL
DEXTROMETHORPHA) MIDE (UNII: 9 D2RTI9 KYH) ROTS)		DEXTRO METHO RPH HYDRO B RO MIDE	HAN	10 mg in 15 mL
GUAIFENESIN (UNII: 4	95W7451VQ) (C	GUAIFENESIN - UNII:495W7451VQ)		GUAIFENESIN		200 mg in 15 mL
PHENYLEPHRINE HYD UNII:1WS297W6MV)	DRO CHLO RIDI	E (UNII: 04JA59TNSJ) (PHENYLEPHRINE	-	PHENYLEPHRINE HYDROCHLORIDE		5 mg in 15 mL
Inactive Ingredie	nts					
		Ingredient Name			S	trength
BUTYLATED HYDRO						
EDETATE DISODIUM						
FD&C YELLOW NO. 6 GLYCERIN (UNII: PDC)		J3A8)				
MENTHOL (UNII: L7T1						
SO DIUM PHO SPHATE		C (UNII: 3980JIH2SW)				
POLYETHYLENE GLY		, ,				
PROPYLENE GLYCO	L (UNII: 6DC9Q	167V3)				
WATER (UNII: 059QF0	KO0R)					
SACCHARIN SODIUM	(UNII: SB8ZUX	40 TY)				
SUCROSE (UNII: C151H	H8 M554)					
XANTHAN GUM (UNII:	TTV12P4NEE)					
Product Characte	ristics					
		E (clear)	Scor			

Shape		Size	
Flavor	FRUIT, MENTHOL	Imprint Code	
Contains			
Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:30142-603-40	354 mL in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Info	ormation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/10/2014	
Marketing Info	ormation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/24/2014	
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Labeler - Kroger Company (006999528)

Revised: 1/2019

Kroger Company