#### NIGHTTIME 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.

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# Kroger Co. DayTime NightTime 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  $^{\mbox{\scriptsize B}}$  DAYQUIL  $^{\mbox{\scriptsize B}}$  SEVERE COLD & FLU & VICKS  $^{\mbox{\scriptsize B}}$  NYQUIL  $^{\mbox{\scriptsize B}}$  SEVERE COLD & FLU

See side panel

Kroger<sub>®</sub>

Maximum Strength DayTime Severe COLD & FLU Acetaminophen Dextromethorphan HBr Phenylephrine HCl Guaifenesin Pain Reliever Fever Reducer **Cough Suppressant** Nasal Decongestant Expectorant **Alcohol Free** Antihistamine Free Non-Drowsy Maximum Strength NightTime Severe COLD & FLU Acetaminophen Dextromethorphan HBr Phenylephrine HCl **Doxylamine Succinate** Pain Reliever Fever Reducer Cough Suppressant Nasal Decongestant Antihistamine Alcohol Free Sugar Free OUR PHARMACIST RECOMMENDED **Berry Flavor** 2 BOTTLES - 12 FL OZ (354 mL) EACH; TOTAL 24 FL OZ (1.5 pt) (708 mL)



Alcohol Free **Antihistamine Free** Non-Drowsy

Expectorant

Antihistamine

Alcohol Free Sugar Free



Berry

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DISTRIBUTED BY THE KROGER CO. CINCINNATI, OHIO 45202 QUALITY GUARANTEE 800-632-6900 www.kroger.com

Company.

GLUTEN FREE

2 BOTTLES - 12 FL OZ (354 mL) EACH; TOTAL 24 FL OZ (1.5 pt) (708 mL) Flavor



#### 59702 45 C6

Hightlime Severe Cold & Flu	
Drug Facts	
Active ingredients (in each 3	30 mL) Purpos
Acetani Inophen 650 mg. Deutromethorphan HBr 20 mg	Pain releventever reduc
Doglamine succinate 12.5 mg	
Phenylephnine HCI 10 mg.	
US88 temporarily relieves common col mesal congestion situs co	id/Nu symptoms: ongestion and pressure
minor aches and pains	ne fever sore throat
<ul> <li>runny nose and sneezing cough a cough to help you sleep reduces</li> </ul>	due to minor throat and bronchial irritation s swelling of nasal passages
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If a skin reaction occurs, stop use and se	ee k medical help right away.
Sime tarivat warning: if sore throat is sev or followed by fever, headache, sach, sa	vere, persists for more than 2 days, is accompanie uses, or vom ling, consult a doctor promptly
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or contact a Poison Control Center right a is critical for adults as well as for children	away (1-800-222-1222). Quick medical attention n even if you do not notice any signs or symptom
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adults & children 12 yrs & over children 4 to under 12 yrs	30 mL every 4 hrs ask a doctor
children under 4 ym	do not use
Other information	
<ul> <li>each 30 mL contains: sodium 41 mg</li> <li>store at 28-25°C (68-77°F)</li> </ul>	
FD&C red #40, flavor, glyc erin, propylere	citric acid, edelate disodium, FD&C blue #1, e glycol, purilled water, seccharin sodium, sodium
benzoale, sodium chiotide, sodium citazi	le, sorbitol solution, susraiose, xanthan guin

Questions or comments?1-800-632-6900

# ytime Seven: Cold & File **Drug Facts** Active ingredients (in each 15 mL) Purpose Actanicophen 825 mg. Pain reieverlever reducer Dechanerhophan HE 10 mg. Coult appresant Exateresti Adv mg. Expectant Phenyliphrite HCI 5 mg. Assal decongestant VISES temporarily releves common cold/lu symptoms: INSES temporarily releves common cold/lu symptoms: In case (congestion III) is a final songestion and pressure III) cough due to misor threat and bronchild inflation III inflation and pressure III inflation III inflation and pressure III inflation III inflation and pressure III inflation III inflation III provides assal and/or sinus drainage III they isolate inflation in us drainage III they isolate inflation in us and make coughs more productive IIII passageways of botherscore muces and make coughs more productive Warnings Liver waning This product contains acetaminophen. Severe liver damage may occur if Liver warning: This product contains activitying the . Severe liver damage may occar if additions more than 4,161 mg of actaintiformen is 24 hours worked takes more than 5 does in 24 hours addition work of the drugs containing actaining the additions 3 or more absolute drives every day while using this product Allergy alart. Acclaminghas may cause server shift reactions. Symptoms may include: with nothing works and a server shift reactions. Symptoms may include: with nothing works and a server shift reactions. Symptoms may include: if a skin reaction occar, stop use and each medical help right away. Some throat warming if service and a lowere, periods for more than 2 days, is accompanied or followed by free; baseleche, sea, nausea, or working, consult a doctor promply. or increase by refer, treatment in the increase or remaining, contain a contain property. Bornot area with any other drug containing acetaminoplen (prescription or nonprescription). If you are notice to whether a drug contains acetaminoplen, site a doctor or pharmadist. If you are not being a prescription monomine condition, or Parkineon's descent, or the 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, site a doctor or pharmadist here being bing reduct. If you are not work of the machine or pharmadist here being bing preduct. If you have ever had an allergic reaction to this product or any officing redients type and the even tool on a table product of the product of any other togetheres Ask a divide the form used if you have when disease in heart disease in thyoid disease disease in heart disease is thyoid disease disease in the third disease is a trypic of the table of table of the table of t or emphysiente. Ask a doctor or pharmaelist before use if you are taking the blood thinning drug wartarin When using this product is not use more than directed Stop use and ask a decitor If you get rerivous, dizzy or sleepless put generative, but you appeare plat, near comparison or cough gets wone or lasts more than 5 days (childrer) or 7 days (chalds) = tever gets wone or lasts more than 3 days = referes or swelling is present = set symptome occur = set symptome occur = outph comes back or occurs with namh or headeche that lasts. These cough comes floations. If programs or travest-fooding, ask a health professional bettere use. Kingo out of mench of children. Overdose winning in save of overdose, get medical help or contexts a healten Control Control forther tight away (-14) He 222-2222, Dukk medical arbertion is critical for adults as well as for children eres if you do not notice any signs or symptoms.

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	Directions	
	take only as directed - see Overdose we monly use the dose cup provided in do	ming notesceed 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 contailes: sodium 6 mg = store at 20-25°C (68-77°F). Do not mitig	gerzie.
Ium	Inactive ingredients outpated by Navor, gipterin, menthol, monotesic sodiu giptol, purified water, secterin sodium, su	dronyanisole, edelate discollum, FD&C yellow #6, n phosphate, polyethylene głycol, propylene szrose, xanthan gum
	Questions or comments?1-800	0-632-6000



# Maximum Strength DayTime **COLD & FLU**

Acetaminophen Dextromethorphan HBr Phenylephrine HCI Guaifenesin

Pain Reliever Fever Reducer Cough Suppressant Nasal Decongestant Expectorant

#### PARENTS: Learn about teen medicine abuse

www.StopMedicineAbuse.org

# NIGHTTIME DAYTIME SEVERE COLD AND FLU

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

Product Inform							
	nation						
Product Type	HUMAN	OTC DRUG	ltem Co	ode (Soui	rce)	NDC:3014	12-597
Packaging							
# Item Code	Pac	kage Descriptio	n		eting Start Date		eting End Date
<b>_</b>		pe 0: Not a Combinat	tion	09/24/201			2410
- 02	Product						
Quantity of Pai Part #	rτs Package Q	Juantity		Та	tal Product Q	Nuantity	
Part 1 1 BOTTLE	гаскауе с	quantity	354 mL			Zuantity	
Part 2 1 BOTTLE			354 mL				
Part 1 of 2							
NIGHTTIME	SEVERE	COLD AND	FLU				
acetaminophen, d	dextrometh	orphan hbr. doxvl	lamine si	uccinate.	phenylephrine	e hcl solu	Ition
Product Inform	nation						
Product Inform		NDC:30142-763					
	e)	NDC:30142-763 ORAL					
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Item Code (Sourc Route of Adminis Active Ingredie	tration ent/Active Ingred	ORAL Moiety lient Name	N - UNII:36	5209ITL9D)	Basis of St	rength	Strength 650 mg
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EDETATE DISODIUM (UNII:	7FLD91C86K)		
FD&C BLUE NO. 1 (UNII: H	3R47K3TBD)		
FD&C RED NO. 40 (UNII: W	ZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0	OX)		
PROPYLENE GLYCOL (UNII	: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)			
SACCHARIN SODIUM (UNII	SB8ZUX40TY)		
SODIUM BENZOATE (UNII:	OJ245FE5EU)		
SODIUM CHLORIDE (UNII: 4	451W47IQ8X)		
SODIUM CITRATE, UNSPE	CIFIED FORM (UNII: 1Q73Q2JULI	२)	
SORBITOL (UNII: 506T60A2	•		
SUCROSE (UNII: C151H8M5	54)		
XANTHAN GUM (UNII: TTV1	2P4NEE)		
<b>Product Characteris</b>	stics		
Color	RED (clear, dark)	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			
Packaging			

#### Packaging

#	ltem 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 Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph final	part341	08/13/2014	

# Part 2 of 2

# DAYTIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

Product Information				
ltem Code (Source)	NDC:30142-603			
Route of Administration	ORAL			
	<b></b>			
Active Ingredient/Active	Molety			

			ngredient Name	Basis of Stre	ength Strengt
ACET			209ITL9D) (ACETAMINOPHEN - UNII:36209		325 mg
		•		• 	in 15 mL
	TROMETHORPH		DROBROMIDE (UNII: 9D2RTI9KYH) :7355X3ROTS)	DEXTROMETHORPH HYDROBROMIDE	in 15 mL
GUAI	IFENESIN (UNI	l: 495W74	451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL
	NYLEPHRINE H 1WS297W6MV)	IYDROC	HLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHI	RINE - PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL
Ina	ctive Ingre	dients	i		
			Ingredient Name		Strength
BUT	YLATED HYDR	OXYANI	SOLE (UNII: REK4960K2U)		
	TATE DISODIU	<b>,</b> -			
	C YELLOW NO				
	CERIN (UNII: PC				
				980JIH25W)	
		-	UNSPECIFIED (UNII: 3WQ0SDW1A)		
		-	· · ·		
	ER (UNII: 059Q				
	CHARIN SODIL Rose (Unii: C1				
	THAN GUM (UN		•		
Pro	duct Chara	acteris	tics		
Colo	or		ORANGE (clear)	Score	
Sha	pe			Size	
Flav	-		FRUIT, MENTHOL	Imprint Code	
	tains				
com					
	kaging				
	kaging			Madadian Charl	
Pac	kaging Item Code		Package Description	Marketing Start Date	Marketing End Date
Pac # I	Item Code	354 mL Product	<b>Package Description</b> in 1 BOTTLE; Type 0: Not a Combination	-	-
Pac # I	Item Code			-	-
Pac # I 1 <sup>NE</sup> 40	Item Code	Product	in 1 BOTTLE; Type 0: Not a Combination	-	-
Pac # I 1 40 Ma	item Code DC:30142-603- )	Product	in 1 BOTTLE; Type 0: Not a Combination	-	-
Pac # I 1 <sup>NE</sup> 40	Item Code	Product Infor Ap	in 1 BOTTLE; Type 0: Not a Combination mation plication Number or Monograph Citation	Date Marketing Start	Date Marketing End
Pac # I 1 <sup>NE</sup> 40	Item Code	Product Infor Ap	in 1 BOTTLE; Type 0: Not a Combination mation plication Number or Monograph Citation	Date Marketing Start Date	Date Marketing End
Рас # I 1 <sup>NE</sup> 40 Ма	Item Code	Product	in 1 BOTTLE; Type 0: Not a Combination mation plication Number or Monograph Citation 441	Date Marketing Start Date	Date Marketing End

09/24/2014

# Labeler - Kroger Company (006999528)

Revised: 6/2023

Kroger Company