DAYTIME NIGHTTIME COLD AND FLU- acetaminophen dextromethorphan hbr phenylephrine hci doxylaminesucinate Rite Aid Corporation

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.

Drug Facts

Active ingredients (in each 15 mL) DAYTIME

Acetaminophen 325 mg Dextromethorphan HBr 10 mg Phenylephrine HCl 5 mg

Active ingredients for (in each 30 mL) NIGHTTIME

Acetaminophen 650 mg Dextromethorphan HBr 30 mg Doxylamine Succinate 12.5 mg

Purposes for Day Time

Pain reliever/fever reducer Cough suppressant Nasal decongestant

Purpose for Night Time

Pain reliever/fever reducer Cough suppressant Antihistamine

Uses

DAYTIME

- temporarily relieves common cold and flu symptoms
 - minor aches and pains
 - headache
 - sore throat
 - nasal congestion

- fever
- cough due to minor throat and bronchial irritation

NIGHTTIME

- temporarily relieves these common cold/flu symptoms`
 - minor aches and pains
 - headache
 - sore throat
 - runny nose and sneezing
 - fever
 - cough due to minor throat and bronchial irritation

Warnings

DAYTIME

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

- adult takes more than 4 doses (30 mL each) of acetaminophen in 24 hours, which is the maximum daily amount
- child takes more than 4 doses (15 mL each) 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.

NIGHTTIME

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

DAYTIME NIGHTTIME

- 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 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if you have

DAYTIME

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- a sodium-restricted diet
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)

NIGHTTIME

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

Ask a doctor or pharmacist before use if you are

DAYTIME

taking the blood thinning drug warfarin.

NIGHTTIME

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

DAYTIME

do not exceed recommended dosage.

NIGHTTIME

- 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

DAYTIME

- nervousness, dizziness or sleeplessness occur
- pain, nasal congestion, or cough gets worse, or lasts more than 5 days(children) or 7 days (adult)
- 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.

NIGHTTIME

- 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.

DAYTIME NIGHTTIME

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center(1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

DAYTIME

- do not take more than directed (see Overdose warning)
- do not take more than 4 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product
- mL= milliliter

adults and children 12 years and over	30 mL every 4 hours
children 6 to under 12 years	15 mL every 4 hours
children 4 to under 6 years	ask a doctor
children under 4 years	do not use

NIGHTTIME

- do not take more than directed (see Overdose warning)
- Do not take more than 4 doses in any 24-hours period
- measure only with dosing cup provided. Do not use any other dosing device.
- mL= milliliter
- keep dosing cup with product
- adults and children 12 years and over: 30 mL every 6 hours
- children under 12 years of age: do not use

Other information

DAYTIME

- each 15 mL contains: sodium 12 mg
- store between 20-25°C (68-77°). Do not refrigerate

NIGHTTIME

- each 30 mL contains: potassium 5 mg
- each 30 mL contains sodium 24 mg
- store between 20-25ºC (68-77ºF). Do not refrigerate

Inactive ingredients

Day Time

citric acid, FD&C yellow #6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride,sodium citrate, sorbitol, sucralose, xantham gum

Night Time

acesulfame potassium, 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 trisodium citrate dihydrate

Questions or comments?

Call 1-888-723-3929 Monday-Friday 9AM-5PM EST

Principal Display Panel

DAYTIME

Compare to the active ingredients in Vicks® DayQuil® Cold & Flu*

MULTI-SYMPTOM

DAYTIME

COLD & FLU RELIEF

ACETAMINOPHEN 325 mg

DEXTROMETH HBr 10 mg

PHENHYDRAMINE HCI 5 mg

PAIN RELIEVER / FEVER REDUCER

COUGH SUPPRESSANT

NASAL DECONGESTANT

Relieves aches, fever, sore throat

Cough • Nasal congestion

NON-DROWSY • ALCOHOL FREE

ANTIHISTAMINE FREE

For ages 6 years & over

when using Daytime or Nighttime products, carefully read each label to ensure correct dosing

Compare to the active ingredients in Vicks® NyQuil® Cold & Flu*

NIGHTTIME

COLD & FLU RELIEF

ACETAMINOPHEN 650 mg

DEXTROMETHORPHAN HBr 30 mg

DOXYLAMINE SUCCINATE 12.5 mg

PAIN RELIEVER / FEVER REDUCER

COUGH SUPPRESSANT

ANTIHISTAMINE

Relieves headache, fever, sore throat, minor aches & pains

Sneezing • Running nose • Cough

10% Alcohol

For ages 12 years & over

CHERRY FLAVOR

FL OZ (mL)

*This product is not manufactured or distributed by The Procter & Gamble Company. Vicks®, DayQuil® and NyQuil® are registered trademarks of The Procter & Gamble Company.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

DISTRIBUTED BY

RITE AID, 30 HUNTER LANE,

CAMP HILL, PA 17011

www.riteaid.com

Product Label



RITE AID Multi-Symptom Daytime Nighttime Cold & Flu Relief

DAYT		GHTTIME COLD AND	FLU		
acetami	nophen de	extromethorphan hbr phenyle	ephrine	hci doxylaminesucinat	e kit
Produ	ct Inforn	nation			
Produc	t Type	HUMAN OTC DRUG	ltem Co	de (Source)	NDC:11822-8555
Packa	aina				
	m Code	Package Description	n	Marketing Start Date	Marketing End Date
1 NDC:1	.1822-8555-	1 in 1 KIT; Type 0: Not a Combinat Product	tion	05/28/2021	
Quant	ity of Pa	rts			
Part #		Package Quantity		Total Product	Quantity
Part 1	1 BOTTLE		355 mL	•	
Part 2	1 BOTTLE		355 mL		
Part	1 of 2				

DAYTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid

Produc	t Inform	ation					
Item Cod	le (Source	e)	NDC:11822-1583				
Route of	f Administ	ration	ORAL				
Active I	ngrediei	nt/Active					.
		Ingred	lient Name		Basis of Stre	ength	Strength
ACETAMI	NOPHEN (U	NII: 36209ITL	9D) (ACETAMINOPHEN - UNII:36209	9ITL9D)	ACETAMINOPHEN		325 mg in 15 mL
		AN HYDROBE - UNII:7355X	ROMIDE (UNII: 9D2RTI9KYH) 3ROTS)		DEXTROMETHORPH HYDROBROMIDE	IAN	10 mg in 15 mL
PHENYLEI UNII:1WS29		DROCHLORI	DE (UNII: 04JA59TNSJ) (PHENYLEPH	IRINE -	PHENYLEPHRINE HYDROCHLORIDE		5 mg in 15 mL
Inactive	e Ingredi	ients					
			Ingredient Name			St	trength
		ACID (UNII: >					
FD&C YEI	LOW NO.	6 (UNII: H77V	EI93A8)				
PROPYLE	NE GLYCOL	. (UNII: 6DC90	Q167V3)				
WATER (U	NII: 059QF0	KO0R)					
TRISODIU	M CITRATE	DIHYDRATE	(UNII: B22547B95K)				
	I (UNII: PDC6						
		(UNII: SB8ZU					
		(UNII: OJ245F					
		UNII: 451W47	IQ8X)				
	L (UNII: 5061						
		K6UQ3ZD4) TTV12P4NEE	<u>۸</u>				
Packag	ing						
# Iten Cod	-	Pack	age Description	Mar	keting Start Date		eting End Date
1	355 m Packag		E; Type 1: Convenience Kit of Co-				
Marke	ting In	format	ion				
	eting egory	Applicat	tion Number or Monograph Citation	Ma	rketing Start Date		eting End Date
OTC mono	graph final	part341		05/28	3/2021		

Part 2 of 2

NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid

Product Information NDC: 11822-3318 Route of Administration OPAL Active Ingredient/Active Molety Active Ingredient/Active Molety Basis of Strength Strength Active Ingredient/Active Molety ActertaminoPhen (unit: 362091TL90) ActertaminoPhen (unit: 362091TL90) DEXTROMETHORPHAN HYDROBROBIDE (UNIt: 9021719XYH) DEXTROMETHORPHAN HYDROBROBIDE (UNIt: 9021719XYH) DEXTROMETHORPHAN HYDROBROBIDE (UNIt: 9021719XYH) DEXTROMETHORPHAN HYDROBROBIDE (UNIt: 9021719XYH) DEXTROMETHORPHAN HYDROBROBIDE (UNIt: 9201719XYH) DEXTROMETHORPHAN HYDROBROBIDE (UNIt: 9201719XYH) DEXTROMETHORPHAN HYDROBROFIDE (UNIt: 9201719XYH) DEXTROMETHORPHAN HYDROBROFIDE (UNIt: 9201719XYH) DEXTROMETHORPHAN HYDROBROFIDE (UNIt: 9201719X) Ingredient Name Strength Actes (UNIt: 1001111 X41703780) DEXTROMETHORPHAN HYDROBROFIDE (UNIt: 8207303056) FROPULENE GLYCOL (UNIt: B437/5780) Strength FROPULENE GLYCOL (UNIt: B437/5780) Strength FROPULENE GLYCOL (UNIT: 8207302665) FROPULENE GLYCOL (UNIT: B22547895K) <th colspa<="" th=""><th></th><th></th><th></th><th></th><th></th><th></th><th></th></th>	<th></th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th>							
OPAL Active Ingredient/Active Molety Active Ingredient/Active Molety Strength DextRomeTHORPHAN HYDROBROMIDE (UNII: 392RT19KYH) DextRomeTHORPHAN UNII: 35209TL9D) (ACETAMINOPHEN - UNII: 36209TL9D) (ACETAMINOPHEN - UNII: 35209TL9D) (IDOXYLAMINE - UNII: 352978X9TS) DoXYLAMINE SUCCINATE (UNII: YB91985Y12) (DOXYLAMINE - UNII: 3620971KPL) Ingredient Name Strength Active Ingredients Strength Ingredient Name Strength Active Ingredients Strength Ingredient Name Strength Active Ingredients Strength Ingredient Name Strength Active Ingredient Name Strength Active Ingredient Name Strength Active Ingredients Strength Actingr	Product Inform	ation						
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Ingredient Name Basis of Strength Strength ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN 650 mg in 30 mL DEXTROMETHORPHAN HYDROBROMIDE (UNII: 902RTI9KYH) DEXTROMETHORPHAN - UNII:355X3R0T5) DEXTROMETHORPHAN - UNII:355X3R0T5) DEXTROMETHORPHAN - UNII:355X3R0T5) DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) DEXTROMETHORPHAN - UNII:355X3R0T5) DEXTROMETHORPHAN - UNII:350X3R0T5) DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) DEXTROMETHORPHAN - UNII:3620913 12.5 mg in 30 mL Inactive Ingredients Ingredient Name Strength ACESULFAME POTASSIUM (UNII: 320V73Q5G9) AAHYDROUS CITRIC ACID (UNII: 8247703P5L) ALCOHOL (UNII: 324958900M) FD&C BLUE NO. 1 (UNII: H3R47K3TBD) FD&C RED NO. 40 (UNII: WZ B9127X0A) HIGH FRUCTOSE CORN SYRUP (UNII: X9050X0265) PROPYLENE GLYCOL (UNII: EDESQU507V3) WATER (UNII: 05090F0KO0R) POLYETHYLENE GLYCOL (UNII: EDESQU50V2A) RISODIUM CITRATE DIHYDRATE (UNII: 32042547895K) SACCHARIN SODIUM (UNII: SB8ZUX40TY) SCore Shape Size Size Size Size Flavor CHERRY Imprint Code Contains Size Size	Route of Administ	ration	ORAL					
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WATER (UNII: 059QF0K00R) Image: Section of the se	HIGH FRUCTOSE CO	RN SYRUP (UNII: XY6UN3QB6S)					
PolyETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDWLA) TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K) SACCHARIN SOTUM (UNII: SB8ZUX40TY) Product Characteristics Color Score Shape Size Flavor CHERRY Imprint Code Protectaging	PROPYLENE GLYCOL	(UNII: 6DC9	Q167V3)					
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K) SACCHARIN SODIUM (UNII: SB8ZUX40TY) Score Score Solum colspan="2">Color Solum colspan="2">Score Shape Size Flavor CHERRY Imprint Code Contains Marketing Start Marketing Start Marketing Start # Item Code Marketing Start J 355 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-	WATER (UNII: 059QF0I	KO0R)						
SAC CHARIN SODIUM (UNII: SB8ZUX40TY) Product Characteristics Color Shape Size Flavor CHERY Imprint Code Contains CHERY Kem Code Package Description Marketing Start Date Marketing End Date 1 355 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-	POLYETHYLENE GLY	COL, UNSPE	ECIFIED (UNII: 3WJQ0SDV	VIA)				
Product Characteristics Color Score Shape Size Imprint Code Flavor CHERRY Imprint Code Contains Packaging Marketing Start Date Marketing End Date 355 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-	TRISODIUM CITRATE	DIHYDRATI	E (UNII: B22547B95K)					
Color Score Score Size	SACCHARIN SODIUM	(UNII: SB8Z	UX40TY)					
Color Score Score Size								
Shape Size Flavor CHERRY contains Imprint Code Package Description Marketing Start Marketing End Date 355 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-	Product Charact	teristics						
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			E; Type 1: Convenience k	Kit of Co-				

Marketing Ir	formation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/28/2021	
Marketing Ir	formation		
Marketing Ir Marketing Category	Iformation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

Labeler - Rite Aid Corporation (014578892)

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Rite Aid Corporation