DAYTIME NIGHTTIME COLD FLU RELIEF- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl 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 for Daytime (in each softgel) Acetaminophen 325 mg

Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

Active ingredients for Nighttime (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg
Doxylamine succinate 6.25 mg

Purpose for Daytime

Pain reliever/fever reducer

Cough suppressant Nasal decongestant

Purpose for Nighttime

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Uses

DAYTIME

- temporarily relieves common cold and flu symptoms
 - cough due to minor throat and bronchial irritation
 - nasal congestion
 - headache
 - minor aches and pains

- fever
- sore throat

NIGHTTIME

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

Warnings

DAYTIME

Liver warning: These products contain 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 these products

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 contain 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

Alergy 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 following by fever, headache, rash, nausea, vomiting, consult a doctor promptly.

Do not use

DAYTIME

- 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.

NIGHTTIME

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- 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

DAYTIME

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

NIGHTTIME

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

Ask a doctor or pharmacist before use if you are

DAYTIME

taking the blood thinning drug warfarin

NIGHTTIME

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

When using this product,

DAYTIME

do not exceed recommended dosage

NIGHTTIME

- do not exceed recommended dosage
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

DAYTIME

- nervousness, dizziness or sleeplessness occur
- pain, cough, and nasal congestion gets worse or lasts more than 7 days
- redness or swelling is present
- new symptoms occur
- fever gets worse or lasts more than 3 days
- 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 headache that lasts. These could be a signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: Taking more than the recommended dose can 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 24 hours
- swallow whole; do not crush, chew, or dissolve
- adults and children 12 years and over; take 2 softgels with water every 4 hours.
- children under 12 years: do not use

NIGHTTIME

- do not take more than directed (see Overdose warning)
- do not take more than 4 doses in 24 hours
- swallow whole; do not crush, chew, or dissolve
- adults and children 12 years and over: take 2 softgels with water every 6 hours
- children under 12 years: do not use

Other information

- store between 15-30°C (59-86°F)
- avoid excessive heat

Inactive ingredients

DAYTIME

butylated hydroxyanisole, butylated hydroxytoluene, FD&C yellow #6, gelatin, glycerin, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, white ink

NIGHTTIME

D&C yellow #10, FD&C blue #1, gelatin, glycerin, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan*, sorbitol, white ink

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredients in Vicks ${\tt @}$ DayQuil ${\tt @}$ and NyQuil ${\tt @}$ Cold & Flu LiquiCaps ${\tt @}$

MULTI-SYMPTOM COLD & FLU RELIEF

DAYTIME

ACETAMINOPHEN 325 mg

DEXTROMETHORPHAN HBr 10 mg

PHENYLEPHRINE HCL 5 mg

PAIN RELIEVER / FEVER REDUCER

COUGH SUPPRESSANT

NASAL DECONGESTANT

NON-DROWSY

Temporarily relieves aches, fever & sore throat

Cough • Nasal congestion

Antihistamine-free

Alcohol-free

DAYTIME

SOFTGELS**

LIQUID FILLED CAPSULES

NIGHTTIME

ACETAMINOPHEN 325 mg

DEXTROMETHORPHAN HBr 15 mg

DOXYLAMINE SUCCINATE 6.25 mg

PAIN RELIEVER / FEVER REDUCER

COUGH SUPPRESSANT

ANTIHISTAMINE

Temporarily relieves aches, fever & sore throat

Cough,

Runny nose & sneezing

Alcohol-free

NIGHTTIME

SOFTGELS**

**LIQUID FILLED CAPSULES

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TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOW SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

DISTRIBUTED BY:

RITE AID

30 HUNTER LANE,

CAMP HILL, PA 17011

www.riteaid.com

Product Label

nopos sult sidus or symptoms. uogos suà sidue or symptoms. dical attention is critical for adults as well as for children even if you do not medical attention is critical for adults as well as for children even if you do not help or contact a Polson Control Center (1-800-222-1222) right away. Duick NOME OF CONTRACT & POISON CONTROL (1-600-1222) 1971 ASTRONO 10000 LO GIBRO recommended dose can cause liver damage, in case of overdose, get medical If pregnant or breast-leeding, ask a health professional before use. Keep out of reach of children. Overdose warning: Taking more than the If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children, Overdose warning: Taking more than the Lucse conjq pe signs of a serious condition. Livese could be signs of a serious condition. cough comes back or occurs with rash or headache that lasts. cough comes back or occurs with rash or headache that lasts. Ledness or swelling is present
 new symptoms occur ■ fever gets worse or lasts more than 3 days ■ Tever gets worse or lasts more trian 3 days ■ bein, cough, or nasal congestion gets worse or lasts more than 7 days ■ beju or cough gets worse or lasts more than 7 days Stop use and ask a doctor if ■ nervousness, dizziness, or sleeplessness occur Stop use and ask a doctor if pe causini when driving a motor vehicle or operating machinery
 a sicopol, sedatives, and transmitters may increase drowsiness ■ marked drowsiness may occur ■ avoid alcoholic drinks excitability may occur, especially in children drug wartarin. When using this product a do not exceed recommended dosage ■ taking the blood thinning drug warfarin ■ taking sedatives or tranquitizers Ask a doctor or pharmacist before use if you are ■ pueig state uninating due to an enlarged prostate gland puejó ajetsoud pačuejua ue ot anp butjeuun ajgnout ведиша, спголіс бголспібь, от етірпучета assasib bionyrib = SBIBORIO . s prestring problem or chronic cough that lasts such as occurs with smoking, ■ liver disease ■ heart disease condp that occurs with too much phiegm (mucus) Ask a doctor before use if you have Ask a doctor before use if you have m liver disease m glaucoma pharmacist before taking this product. busumscraf perone taking this product. not know if your prescription drug contains an MAOI, ask a doctor or (certain drugs for depression, psychiathc, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug, If you do if you are now taking a prescription monoamine oxidase inhibitor (MAO)) SEK S DOCTOR OF PREFITED SEELE ask a doctor or pharmacist. ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen,

Drug Facts (continued)

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Drug Facts

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59 00

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If you're not satisfied, we'll happily refund your money.

GUARANTEE

DISTRIBUTED BY:
RITE AID
30 HUNTER LANE,
CAMP HILL, PA 17011

WARNINGS AND PRODUCT

PLD-C570A FC005819

I USE IF CARTON IS OR SHOWS ANY S

BROKEN

EVIDENT: 0 CARTON

Nighttime Cold & Flu Softgel

When using this product, do not exceed recommended dosage.

Ask a doctor or pharmacist before use if you are taking the blood thinning

- becaseour of chronic cough such as occurs with smoking, astrona, or
 - condip gust occruz with too much bijedm (muchs)
 - aunssaud poold right

(certain dings for depression, psychiable, 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

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI)
- nonprescription), if you are not sure whether a drug contains acetaminophen, m with any other drug containing acetaminophen (prescription or

Dung Facts (continued) Daytime Cold & Flu Softgel

3 or more alcoholic drinks every day while using this product

occur if you take: more than 4,000 mg of acetaminophen in 24 hours

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

ecough due to minor throat and bronchial irritation masal congestion Naes • pemporantly relieves common cold and flu symptoms:

sore throat

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Cough suppressant

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в достал втотрау. accompanied or followed by fever, headache, rash, nausea, or vomiting, consult accompanied or followed by fever, headache, rash, nausea, or vomiting, consult 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 Sore throat warning: If sore throat is severe, persists for more than 2 days, is include: # skin reddening # blisters # rash Allergy alert. Acetaminophen may cause severe skin reactions. Symptoms may

il a skiu usecnou occnuz° alob nae suq aeek useqical pejb ulbig swaiv iucinge: ■ skiu uegoeulub ■ piisteus ■ usap Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may

3 or more alcoholic drinks every day while using this product with other drugs containing acetaminophen

occni il you take: ■ more than 4,000 mg of acetaminophen in 24 hours Liver warming: This product contains acetaminophen, Severe liver damage may

minor aches and pains metwer minny nose & sneezing Leough due to minor throat and bronchial initiation symptoms:

Nighttime Cold & Flu Softgel

TOWN OF THE STOCK OF THE PARTY AUDINSTAINT Cough suppressant Dextromethorphan HBr 15 mg. reliever/fever reduce Active ingredients (in each softgel)

Purposes

Active ingredients (in each softgel)

Раборитов ИСІ 5 тд.

Dextromethorphan HBr 10 mg.

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Drug Facts Daytime Cold & Flu Softgel

■ peadache ■ minor aches and pains ■ fever

Compare to the active ingredients in Vicks® DayQuil® and NyQuil® Cold & Flu LiquiCaps®

MULTI-SYMPTOM



ACETAMINOPHEN 325 mg DEXTROMETHORPHAN HBr 15 mg DOXYLAMINE SUCCINATE 6.25 mg

PAIN RELIEVER / FEVER REDUCER COUGH SUPPRESSANT ANTIHISTAMINE

Temporarily relieves aches, fever & sore throat

ACTUAL SIZE

Cough Runny nose & sneezing Alcohol-free

Cough • Nasal congestion

NIGHTTIME SOFTGELS" *LIQUID FILLED CAPSULES

Temporarily relieves aches, fever

Antihistamine-free Alcohol-free

ACTUAL SIZE



8

ACETAMINOPHEN 325 mg

DEXTROMETHORPHAN HBr 10 mg PHENYLEPHRINE HCI 5 mg PAIN RELIEVER / FEVER REDUCER

COUGH SUPPRESSANT NASAL DECONGESTANT

RITE When using Daytime and Nighttime products, carefully read the labeling to ensure correct dosing

Vicks®, DayQuill®, NyQuill®, and LiquiCaps® are registered trademarks of The Procter and Gamble Company. This product is not manufactured or distributed by The Procter & Gamble Company. Call 1-877-753-3935 Monday-Friday 9AM-5PM EST Call 1-877-753-3935 Monday-Friday 9AM-5PM EST Questions or comments? Questions or comments? glycol, povidene, propylene glycol, purfied water, sorbitan, sorbitol, white ink acipital, white ink sorbital, white ink hydroxytoluene, FD&C yellow #6, gelabn, glycenn, mannitol, polyethylene INACTIVE INGredients butylated hydroxyanisole, butylated Inactive ingredients D&C yellow #10, FD&C blue #1, gelatin, glycerin, ■ store between 15-30°C (59-86°F) ■ svoid excessive heat ■ store between 15-30°C (59-86°F) ■ svoid excessive heat польтотпі тэльо Other information ■ children under 12 years; do not use children under 12 years: do not use ■ swallow whole; do not crush, chew, or dissolve ■ adults and children 12 years and over: take 2 softgels with water every 6 hours swallow whole; do not crush, chew, or dissolve
 solutis and children 12 years and over: take 2 sofigels with water every 4 hours ■ do not take more than 4 doses in 24 hours ■ do not take more than 4 doses in 24 hours ■ do not take more than directed (see Overdose warning) ■ do not take more than directed (see Overdose warning) Directions Directions Drug Facts (continued) Nighttime Cold & Flu Softgel Drug Facts (continued) Daytime Cold & Flu Softgel

RITE AID Multi-Symptom Cold & Flu Relief

DAYTIME NIGHTTIME COLD FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:11822-0851

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0851-	1 in 1 KIT; Type 0: Not a Combination Product	08/30/2019	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	8 BLISTER PACK	8
Part 2	16 BLISTER PACK	16

Part 1 of 2

NIGHTTIME COLD FLU RELIEF

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	ACETAMINOPHEN	325 mg

DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients		
Ingredient Name	Strength	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE (UNII: FZ 989GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SORBITAN (UNII: 6092ICV9RU)		
SORBITOL (UNII: 506T60A25R)		
MANNITOL (UNII: 30WL53L36A)		

Product Characteristics				
Color	green	Score	no score	
Shape	CAPSULE	Size	20mm	
Flavor		Imprint Code	P30	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1		8 in 1 CARTON				
1		1 in 1 BLISTER PACK; 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	08/30/2019		

Part 2 of 2

DAYTIME COLD FLU RELIEF

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule

Product Information

Route of Administration

ORAL

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

Inactive Ingredients	
Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6092ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics				
Color	orange	Score	no score	
Shape	CAPSULE	Size	20mm	
Flavor		Imprint Code	P19	
Contains				

Packaging							
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date			
1		16 in 1 CARTON					
1		1 in 1 BLISTER PACK; 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	08/30/2019					

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph final	part341	08/30/2019					

Labeler - Rite Aid Corporation (014578892)

Revised: 2/2023 Rite Aid Corporation