DAYTIME NIGHTTIME COLD AND COUGH- acetaminophen, dextromethorphan hbr, phenylephrine hcl, doxylamine succinate Walgreens

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 common cold/flu symptoms
 - $\circ~$ minor aches and pain
 - headache
 - sore throat
 - runny nose and sneezing
 - fever
 - cough due to minor throat and bronchial irritations as may occur with a cold

Warnings

DAYTIME NIGHTTIME

Liver warning: This product contain 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.

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 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 contain an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if have

DAYTIME

- liver disease
- high blood pressure
- heart disease
- 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 enlarged prostate gland
- a breathing problem or chronic cough that lasts or occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if the child is

DAYTIME

if you are 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
- mark 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.persists for more than 7 days, comes back or occurs with a fever, rash or persistent headache.

These could be signs of a serious condition.

NIGHTTIME

- pain or cough 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.

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 (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 adult 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

adult 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-hour period
- measure only with dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product
- mL= milliliter
- adult 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°F). Do not refrigerate.

NIGHTTIME

• each 30 mL contains: potassium 5 mg

- each 30 mL contains: sodium 19 mL
- store between 20-25°C (68-77°F). Do not refrigerate

Inactive ingredients

DAYTIME

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

NIGHTTIME

acesulfame potassium, alcohol, anhydrous citric acid, D&C yellow #10 FD&C green #3, FD&C yellow #6, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, trisodium citrate dihydrate

Questions or comments?

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

Principal Display Panel

Compare to the active ingredients in Vick $\ensuremath{^{\ensuremath{\mathbb R}}}$ Dayquil $\ensuremath{^{\ensuremath{\mathbb R}}}$ Cold & Flu & Vick $\ensuremath{^{\ensuremath{\mathbb R}}}$ Nyquil $\ensuremath{^{\ensuremath{\mathbb R}}}$ Cold & Flu††

DAYTIME • NON-DROWSY

Cold & Cough

ACETAMINOPHEN 325 mg / PAIN RELIEVER / FEVER REDUCER

DEXTROMETHORPHAN HBr 10 mg / COUGH SUPPRESSANT

PHENYLEPHRINE HCI 5 mg / NASAL DECONGESTANT

Multi-Symptom

- Relieves aches, fever, & sore throat, cough & nasal congestion
- For ages 6 years & over
- Alcohol free
- Antihistamine free

FL OZ (mL)

NIGHTTIME

Cold & Flu

ACETAMINOPHEN 650 mg / PAIN RELIEVER / FEVER REDUCER

DEXTROMETHORPHAN HBr 30 mg / COUGH SUPPRESSANT

DOXYLAMINE SUCCINATE 12.5 mg / ANTIHISTAMINE

Multi-Symptom

• Relieves headache, fever, sore throat, minor aches & pains, sneezing, runny nose &

cough

- For ages 12 years & over
- Nighttime relief
- ALCOHOL 10%

FL OZ (mL)

WHEN USING OTHER DAYTIME OR NIGHTTIME PRODUCTS, CAREFULLY READ EACH LABEL TO ENSURE CORRECT DOSING

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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DISTRIBUTED BY: WALGREEN CO.

200 WILMOT RD., DEERFIELD, IL 60015 walgreens.com

Product Label



WALGREENS Daytime Non-Drowsy Cold & Flu, Nighttime Cold & Flu

DAYTIME NIGHTTIME COLD AND COUGH acetaminophen, dextromethorphan hbr, phenylephrine hcl, doxylamine succinate kit **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:0363-4670 Packaging Marketing End **Marketing Start Item Code Package Description** Date Date - NDC:0363-4670- 1 in 1 KIT: Type 0: Not a Combination

1 24	Product	07/30/2020		
Quantity of Parts				
Part #	Package Quantity	Total Product Quantity		
i ai c n	Fackage Quantity			
	1 BOTTLE	355 mL		

Part 1 of 2

COLD AND FLU RELIEF

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid

Product Information

Item Code (Source)	NDC:0363-4661
Route of Administration	ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	ACETAMINOPHEN	325 mg in 15 mL		
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL		

Inactive Ingredients				
Ingredient Name	Strength			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
GLYCERIN (UNII: PDC6A3C0OX)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SORBITOL (UNII: 506T60A25R)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
XANTHAN GUM (UNII: TTV12P4NEE)				

Packaging

#	Code	Pacl	kage Description	Marketing Start Date		ate
1		355 mL in 1 BOTT Product	LE; Type 0: Not a Combination			
		Product				
Ma	rketir	ng Informat	tion			
Marketing Application Number or Monograph Marketing Start Marketin						
	Categor	У	Citation	Date		ate
этс	Monograp	h Drug M012		07/30/2020		
Pa	rt 2 of	2				
		D FLU NIC				
			horphan hydrobromide, doxylai	mine succinate liquic	4	
ace	tarninopi	ien, dexiometi	Torphan Hydrobronnide, doxyla		L	
Pro	oduct In	formation				
lten	n Code (S	Source)	NDC:0363-3430			
		ministration	ORAL			
∆ct	ive Inar	edient/Active	Moietv			
	ive nigi		dient Name	Basis of Str	enath	Strengt
AC E	TAMINOPI		L9D) (ACETAMINOPHEN - UNII:362091			650 mg in 30 mL
			BROMIDE (UNII: 9D2RTI9KYH)	DEXTROMETHORP	PHAN :	30 mg
•		RPHAN - UNII:7355	X3R015) V9BI9B5YI2) (DOXYLAMINE -	HYDROBROMIDE		in 30 mL 12.5 mg
	95QB77JKP			DOXYLAMINE SUC	CINATE	in 30 mL
Ina	ctive In	gredients				
			Ingredient Name		St	trength
		POTASSIUM (UNII				
			XF417D3PSL)			
		II: 3K9958V90M)	WELICO2C)			
		NO. 10 (UNII: 355				
		NO. 3 (UNII: 3P301 V NO. 6 (UNII: H77				
		LYCOL (UNII: 6DC				
		D59QF0KO0R)	, <u>, , , , , , , , , , , , , , , , , , </u>			
** ^			re (UNII: B22547B95K)			
			(UNII: XY6UN3QB6S)			
TRIS	I FRUCTO	SE CUBN CADIID				
TRIS HIGH						
TRIS HIGH POL	YETHYLEN		PECIFIED (UNII: 3WJQ0SDW1A)			

Packaging							
# Item Code	Package Description		Marketing Start Date	Marketing End Date			
	355 mL in 1 BOTTLE; Type 0: Not a Combination Product						
Marketing	Marketing Information						
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC Monograph Drug		M012	07/30/2020				
Marketing	j In	formation					
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC Monograph	Drug	M012	07/30/2020				

Labeler - Walgreens (008965063)

Revised: 5/2024

Walgreens