WALGREENS NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled WALGREEN 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.

Walgreens NightTime Cold and Flu

Drug Facts

Active ingredients (in each softgel)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan Hydrobromide 15 mg	Cough suppressant
Doxylamine Succinate 6.25 mg	Antihistamine

Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches/pains
- fever
- runny nose and sneezing

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4 doses in 24 hours, which is the maximum daily amount for this product.
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Sore throat warning

If sore throat is severe, lasts for more than 2 days, or occurs with or is followed by fever, headache, rash, nausea, or vomiting, see 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.
- to make a child sleep

Ask a doctor before use if you have

- liver disease
- glaucoma

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

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 with driving a motor vehicle or operating machinery
- alcohol, sedatives and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- 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.

Overdose warning

Taking more than the recommended dose can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center 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

- Take only as recommended—see Overdose warning.
- do not exceed 4 doses per 24 hours

adults and children 12 years of age	swallow 2 softgels with water
and over	every 6 hours
children 4 to under 12 years of age	ask a doctor
children under 4 years of age	do not us e

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

Other information

■ store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat

Inactive ingredients

D&C Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide

Questions or comments?

1-888-333-9792

DISTRIBUTED BY: WALGREEN CO. 200 WILMOT RD., DEERFIELD, IL 60015

PRINCIPAL DISPLAY PANEL

Walgreens

Cold & Flu

COMPARE TO ACTIVE INGREDIENTS IN VICKS® NYQUIL® LiquiCaps® active ingredients††

MULTI-SYMPTOM

NIGHTTIME COLD & FLU

- Acetaminophen 325mg/ ACHES/ FEVER/ SORE THROAT
- Dextromethorphan HBr 15mg/COUGH
- Doxylamine Succinate 6.25mg/ SNEEZING/ RUNNY NOSE

Relieves aches, fever, sore throat, cough, sneezing & runny nose

Actual Size

16 LIQUID CAPS

†††† This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademarks Vicks® NyQuil® LiquiCaps®



Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-1168
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	325 mg	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg	
DO XYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DO XYLAMINE - 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 400 (UNII: B697894SGQ)		
PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SORBITOL (UNII: 506T60A25R)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Product Characteristics			
Color	green	Score	no score
Shape	CAPSULE (SOFTGELS)	Size	20 mm
Flavor		Imprint Code	215
Contains			

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:0363-1168-16	2 in 1 CARTON	10/31/2019	
l	1	8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
	1			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/31/2019	

Registrant - SPIRIT PHARMACEUTICALS LLC (179621011)

Revised: 12/2020 WALGREEN COMPANY