NIGHTTIME COLD AND FLU RELIEF- acetaminophen, dextromethorphan hydrobromide, 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.

Walgreen Co. Nighttime Cold & Flu Relief Drug Facts

Active ingredients (in each liquid cap)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Uses

temporarily relieves common cold and flu symptoms:

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

Warnings

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

- more than 8 liquid caps in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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.

Ask a doctor before use if you have

- liver disease
- glaucoma
- trouble urinating due to an enlarged prostate gland
- 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

Ask a doctor or pharmacist before use if you are

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

When using this product

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

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 (overdose) may cause liver damage. 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

- do not take more than directed (see overdose warning)
- do not take more than 8 liquid caps in 24 hours
- adults and children 12 years and over: take 2 liquid caps with water every 6 hours
- children under 12 years: do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.

Other information

- store at controlled room temperature 15°C to 30°C (59°F to 86°F)
- see end flap for expiration date and lot number

Inactive ingredients

D&C yellow #10*, edible ink, FD&C blue #1*, FD&C green #3*, gelatin, glycerin, polyethylene

glycol, povidone, propylene glycol, purified water, sorbitol, * contains one or more of these ingredients

Questions or comments?

1-800-706-5575

Principal Display Panel

MULTI-SYMPTOM NIGHTTIME

Cold & Flu Relief

Acetaminophen / Aches / Fever / Sore throat

Dextromethorphan HBr / Cough

Doxylamine Succinate / Sneezing / Runny Nose

Compare to Vicks[®] NyQuil[®] active ingredients[‡]

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Inseemgue rigued animateirithA Dextromethorphan HBr 15 mg Active ingredients (in each liquid cap)

PRODUCT IN FORMATION Drug Facts

walgreens.com © 2012 Watgreen Co. MADEIN CANADA

100% SATISFACTION

DISTRIBUTE DBY: WALGREEN CO.

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Drug Facts (continued)

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WALGREENS PHARMACIST RECOMMENDED*

ORGOST

Cold & Flu Relief

MULTI-SYMPTOM

Acetaminophen / Aches / Fever / Sore Throat Dextromethorphan HBr / Cough Doxylamine Succinate / Sneezing / Runny Nose

> Compare to Vicks® NyQuil® LiquiCaps® active ingredients#





6 LIQUID CAPS

> Vicks MyQuil LiquiCaps .. His product is not manufactured or distributed by Procer & Gamble, owner of the registered tradements *Walgreens Pharmacist Survey Study, November 2010.

> > Questions or comments? 1-800-706-5575

Orug Facts (continued)

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> > Drug Facts (continued)

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TAMPERENDENT: DO NOT USE IF CARTON IS OPENED OR IF BUSTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

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P104136



NIGHTTIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

]	Product Information			
]	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-1005
]	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: 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)		
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)		
PO VIDO NES (UNII: FZ989 GH9 4E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SORBITOL (UNII: 506T60A25R)		

Product Characteristics				
Color	GREEN	Score	no score	
Shape	OVAL	Size	20 mm	
Flavor		Imprint Code	35A	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NI	OC:0363-1005-01	2 in 1 CARTON		
1		8 in 1 BLISTER PACK		
2 NI	OC:0363-1005-02	2 in 1 CARTON		
2		12 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/09/2012	

Labeler - Walgreen Company (008965063)

Revised: 10/2012 Walgreen Company