NITETIME MULTI-SYMPTOM COLD/FLU RELIEF- acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled Greenbrier International

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.

NiteTime Multi-Symptom Liquid Capsules Cold/Flu Relief

Drug Facts

Active Ingredient

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

Purpose

Purpose

Pain reliever/fever reducer

Cough suppressant

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 & 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 daily while using this product

Sore throat warning

If sore throat is severe, lasts for more than 2 days, 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 when driving a motor vehicle or operating machinery
- alcohol, sedatives, & 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 directed 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 & for children even if you do not notice any signs or symptoms.

Directions

- take only as directed see Overdose warning
- do not exceed 4 doses per 24 hrs

Adults & children 12 years and over	2 softgels with water every 6 hrs
Children 4 to under 12 years	ask a doctor
Children under 4 years	do not use

Other information

• store at room temperature

Inactive ingredients

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

Questions?

1-866-467-2748

This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® Nyquil® Cold & Flu Liquicaps®

PRINCIPAL DISPLAY PANEL - 10 Softgel Carton

Assured

Multi-Symptom

NiteTime

Acetaminophen, Doxylamine, Dextromethorphan HBr

Cold/Flu Relief

- Aches & Sore Throat
- Sneezing, Runny Nose
- Cough 10 Softgels

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	Liquid Capsules 10 SOFTGELS	
06948	NDC 33992-0621-0 *Compare to the active ingredients in Vicks Nyquil® Multi-Symptom	TAMPER EVIDENT: This package is safety sealed & child resistant. Use only if blisters are intact. If difficult to open, use scissors.
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Lot Exp:	Cold/Flu Relief • Aches, Fever & Sore Throat • Sneezing, Runny Nose • Cough 10 SOFTGELS	Distributed by: Greenbrier International, Inc. Chesapeake, VA 23320
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NITETIME MULTI-SYMPTOM COLD/FLU RELIEF

acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled

Product Information			
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-0621
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	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)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
polyethylene glycols (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
propylene glycol (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
sorbitol (UNII: 506T60A25R)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	GREEN	Score	no score	
Shape	OVAL	Size	21mm	
Flavor		Imprint Code	RP062	

Contains					
Packaging					
# Item Code	Package Description	Marketin	ig Start Date	Μ	arketing End Date
1 NDC:33992-0621-0	1 in 1 CARTON				
1	10 in 1 BLISTER PACK				
Maxbating Info	v mation				
Marketing Info	rillation				
Marketing Category	Application Number or Monogra	aph Citation	Marketing Start	Date	Marketing End Date
OTC monograph final	part341		0 1/0 4/20 13		

Labeler - Greenbrier International (610322518)

Revised: 1/2014

Greenbrier International