NIGHT TIME MULTI SYMPTOM FLU COLD MEDICINE- acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled Salado Sales, Inc.

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.

CVP 44-660

Active ingredients (in each liquid-filled capsule)

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

Warnings

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

- more than 4,000 mg 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

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

• 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.

- if you have ever had an allergic reaction to this product or any of its ingredients
- to make a child sleepy
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have

- liver disease
- glaucoma
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland

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 beverages
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution 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
- persistent cough lasts for more than one week, tends to recur, or is accompanied by fever, rash, or persistent headache

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.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt 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
- do not take more than 8 capsules per 24 hours
- adults and children 12 years and over: take 2 capsules with water every 6 hours
- children under 12 years: ask a doctor

Other information

- protect from heat, humidity and light
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

D&C yellow #10, edible white ink, FD&C blue #1, gelatin, glycerin, lecithin, mineral oil, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol

Questions or comments?

1-800-426-9391

Principal display panel

CVP®

HEALTH

COMPARE TO VICKS® NYQUIL® COLD & FLU LIQUICAPS® ACTIVE INGREDIENTS*

NIGHT TIME

LIQUID CAPS

MULTI-SYMPTOM FLU • COLD MEDICINE

- ACETAMINOPHEN PAIN RELIEVER/FEVER REDUCER
- DEXTROMETHORPHAN HBr COUGH SUPPRESSANT
- DOXYLAMINE SUCCINATE ANTIHISTAMINE

RELIEVES:

ACHES & PAINS SORE THROAT

COUGH

FEVER SYMPTOMS

ASSOCIATED WITH THE

COMMON COLD & FLU

12 LIQUID CAPS

*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks $^{\mathbb{R}}$ NyQuil $^{\mathbb{R}}$ Cold & Flu LiquiCaps $^{\mathbb{R}}$.

50844 REV0216A66002

Distributed by Salado Sales, Inc.

P.O. Box 6115, Temple, Texas 76503

www.CVPproducts.com

Product of China

Packaged and Quality Assured in the USA

TAMPER EVIDENT: DON NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

Doxylamine succinate 6.25 m Cough suppressant Dextromethorphan HBr 15 mg. Pain reliever/fever reducer

(alusqas bəllit-biupil dəsə ni) Active ingredients

Drug Facts

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts (continued)

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NIGHT TIME LIQUID CAPS

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- DOXYLAMINE SUCCINATE ANTIHISTAMINE



12 LIQUID CAPS

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TAMPER EVIDENT: DO NOT USE IF PACKAGE IS Opened or If Blister unit is torn, broken

RELIEVES

ACHES & PAINS SORE THROAT COUGH FEVER SYMPTOMS

ASSOCIATED WITH THE COMMON COLD & FLU

Questions or comments? 1-800-426-9391

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nund pacts (continued)

B-0226-660-02-RR REV0216A66002

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Drug Facts (continued)

This product is not manufactured or distributed by Procter & Gamble, wwner of the registered trademark Vicks® MyQuit® Cold & Flu LiquiCaps® 10844 REV0216A66002

owner of the registered trademark Vicks 50844 REV0216A66002 Distributed by Salado Sales, Inc. P.O. Box 6115, Temple, Texas 76503 www.CVPproducts.com

USA

Product of China Packaged and Quality Assured in the L

No print/No varnish Lot & Exp date

NIGHT TIME MULTI SYMPTOM FLU COLD MEDICINE

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:57243-660

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength ACETAMINOPHEN (UNII: 36209 ITL9 D) (ACETAMINOPHEN - UNII:36209 ITL9 D) ACETAMINOPHEN 325 mg DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RT19 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) DOXYLAMINE SUCCINATE (UNII: V9 B19 B5Y12) (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)		
MINERAL OIL (UNII: T5L8T28FGP)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PO VIDO NE (UNII: FZ989 GH94E)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
SORBITOL (UNII: 506T60A25R)		
LECITHIN, SO YBEAN (UNII: 1DI56 QDM62)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics				
Color	GREEN	Score	no score	
Shape	OVAL	Size	21mm	
Flavor		Imprint Code	660	
Contains				

ı	Packaging					
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1 NDC:57243-660-02	1 in 1 CARTON	03/01/2015			
l	1	12 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	0 3/0 1/20 15	

Labeler - Salado Sales, Inc. (009830555)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867837	PACK(57243-660)	

Revised: 5/2020 Salado Sales, Inc.