## NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled SMART SENSE (Kmart)

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.

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#### **Drug Facts**

#### Active ingredients (in each softgel)

#### Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

### **Purposes**

#### 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 bronchial irritation

#### **Warnings**

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

- more than 4,000 mg of acetaminophen in 24 hours
- 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

- to make a child sleep
- 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
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough that occurs with too much phlegm (mucus)

#### 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 can cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away **(1-800-222-1222)**. 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 4 doses in 24 hours
- adults and children 12 years and over: take 2 softgels with water every 6 hours
- swallow whole: do not crush, chew, or dissolve
- children under 12 years: do not use
- when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

#### Other information

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

#### **Inactive ingredients**

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

#### Questions or comments?

Call toll free 1-800-842-7886

#### **Principal Display Panel**

Compare to the active ingredients of Vicks® NyQuil® LiquiCaps®†

Multi-Symptom

COLD & FLU

NightTime

#### Acetaminophen

Dextromethorphan Hydrobromide & Doxylamine Succinate

Pain Reliever/Fever Reducer

Cough Suppressant/Antihistamine

**SOFTGELS** 

Distributed by: Kmart Corporation

Hoffman Estates, IL 60179

#### Shop kmart.com

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

#### KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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

#### **Product Label**

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

## Questions or comments? Call toll free 1-800-842-7886

purified water, sorbitan, sorbitol \$1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, Inactive ingredients D&C yellow #10, edible white ink, FD&C blue

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Drug Facts (continued)

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Antihistamine Doxylamine succinate 6.25 mg Cough suppressant Dextromethorphan HBr 15 mg. Purpose Active ingredients (in each softgel)

Drug Facts

NDC 49738-480-24

Multi-Symptom

24 SOFTGELS

Compare to the active ingredients of Vicks® NyQuil® LiquiCaps®†

**Multi-Symptom** 



COMPLETE WARNINGS AND PRODUCT INFORMATION

KEEP OUTER CARTON FOR

I USE IF CARTON II OR SHOWS ANY 8

EVIDENT: DO NOT

**COLD & FLU** 

# NightTime

Acetaminophen Dextromethorphan Hydrobromide & **Doxylamine Succinate** 

✓ Pain Reliever/Fever Reducer

✓ Cough Suppressant/Antihistamine

**ACTUAL SIZE** 



**24** SOFTGELS

Distributed by: Kmart Corporation Hoffman Estates, IL 60179 Shop kmart.com



SATISFACTION GUARANTEE

Thank you for purchasing this quality product. If you are unsatisfied for any reason, return the unused portion to the store for a full refund or call 1-800-842-7886.



PLD-B FC001297

### NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49738-480
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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	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (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 GLYCOLS (UNII: 3WJQ0SDW1A)	
PO VIDO NES (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	GREEN	Score	no score
Shape	CAPSULE	Size	20 mm
Flavor		Imprint Code	P50;94A;35A
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:49738-480-24	2 in 1 CARTON		
1	12 in 1 BLISTER PACK		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part341	12/31/2012		

## Labeler - SMART SENSE (Kmart) (008965873)

**Registrant** - P and L Development of New York Corporation (800014821)

Revised: 12/2012 SMART SENSE (Kmart)