NIGHT-TIME MULTI-SYMPTOM COLD/FLU ORIGINAL- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid
DeMoulas Market Basket

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.

Night-Time - 501

Drug Facts
Active ingredients (in each 30 mL dose cup)

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine Succinate 12.5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Keep out of reach of children

Keep out of reach of children.

Uses

temporarily relieves cold/flu symptoms:
- sore throat
- minor aches and pain
- runny nose and sneezing
- cough due to minor sore throat and bronchial irritation
- headache
- fever

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
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product.

Allergy Alert: Acetaminophen may causesevere skin reactions. Symptoms may include:
- skinreddening
- blisters
- rash

If a skin reactions occurs, stop 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

- 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 sleepy

Ask a doctor before use if you have

- a sodium restricted diet
- 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
- if you are taking the blood thinning drug warfarin

When using this product

- **do not use more than directed**
- avoid alcoholic drinks
- excitability may occur, especially in children
- marked drowsiness may occur
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- redness or swelling is present
- symptoms do not get better within 7 days or are accompanied by a fever
- fever gets worse or lasts more than 3 days
- new symptoms occur
- cough lasts more than 7 days, comes back, or occurs with fever, rash, headache that lasts
- These could be signs of a serious condition.

If pregnant or breast-feeding

ask a health professional before use.

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 warnings
- Use dose cup or tablespoon (TBSP)
- do not exceed 4 doses per 24 hours
- If taking Night Time at night and Day Time during the day, limit total to 4 doses per 24 hours

adults & children 12 years and over	30 mL (2 TBSP) every 6 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

Other information

- **each 30 mL dose cup contains:**
- sodium 45 mg
- store at room temperature

Inactive ingredients

citric acid, D and C yellow No. 10, FD and C Green No. 3, FD and C Yellow No. 6, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose

Questions?

Call weekdays

1-877-798-5944

Market Basket Night-Time product label

MARKET BASKET®

"MORE FOR YOUR DOLLAR"

*** COMPARE TO THE ACTIVE INGREDIENTS IN VICKS® NYQUIL®**

NIGHT-TIME

MULTI-SYMPTOM COLD/FLU RELIEF

Acetaminophen - Pain Reliever/Fever Reducer

Dextromethorphan HBr - Cough Suppressant

Doxylamine Succinate - Antihistamine

Original Flavor

12 FL OZ (354 mL)

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN

Failure to followthese warnings could result in serious complications

*This product is not manufactured or distributed by Proctor & Gamble, distributor of Vicks® Nyquil® LR-002

Made in the USA

DISTRIBUTED BY DEMOULAS SUPERMARKETS INC.

875 EAST STREET - TEWKSBURY, MA 01876

LR - 034 REV 01

NIGHT-TIME MULTI-SYMPTOM COLD/FLU ORIGINAL

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53942-501
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE -	DOXYLAMINE SUCCINATE	12.5 mg

UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	in 30 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53942-501-28	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/01/2012	

Labeler - DeMoulas Market Basket (007869647)

Registrant - AptaPharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(53942-501)

Revised: 3/2017 DeMoulas Market Basket