# NIGHT-TIME MULTI-SYMPTOM COLD/FLU CHERRY- 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.

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Market Basket Night-Time Cherry - 502

# 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:

- skin reddening
- 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

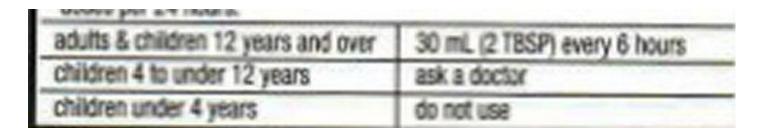
ask a health professional before use.

# **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



#### Other information

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

# **Inactive ingredients**

citric acid, FD and C Blue No. 1, FD and C Red No. 40, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose

### Questions?

Call weekdays

1-877-798-5944

#### **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 - Cough Suppressant

Doxylamine Succinate - Antihistamine

Cherry Flavor

12 FL OZ (354 mL)

### DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN

# Failure to follow these warnings could result in serious consequences

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

Made in the USA

DISTRIBUTED BY: DEMOULAS SUPERMARKETS INC. 875 EAST STREET - TEWKSBURY, MA 01876

LR - 035 REV01



# NIGHT-TIME MULTI-SYMPTOM COLD/FLU CHERRY

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53942-502
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	650 mg in 30 mL	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL	
DO XYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DO XYLAMINE -	DOYVI AMINE SUCCINATE	12.5 mg	

UNII:95QB77JKPL) in 30 mL

Inactive Ingredients		
Ingredient Name	Strength	
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
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)		

Product Characteristics		
Color		Score
Shape		Size
Flavor	CHERRY (Cherry Flavor)	Imprint Code
Contains		

l	Packaging				
ı	# Item Co	de	Package Description	Marketing Start D	ate Marketing End Date
ı	1 NDC:53942-	502-28 354 mL in 1	BOTTLE; Type 0: Not a Combination F	Pro duct 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(53942-502)	

Revised: 3/2017 DeMoulas Market Basket