NIGHT-TIME ORIGINAL MULTI-SYMPTOM COLD/FLU RELIEF- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid
Chain Drug Consortium, LLC

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.

Active ingredients

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

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Uses

temporarily relieves cold/flu symptoms:

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

Warnings

Failure to follow these warnings could result in serious consequences

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.

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

Product Label

NDC 68016-144-01
COMPARE TO THE ACTIVE INGREDIENTS IN VICKS® NYQUIL®

Premier Value®

Original

Night-Time
MULTI-SYMPTOM COLD/FLU RELIEF

Acetaminophen……Pain Reliever/Fever Reducer
Dextromethorphan HBr……Cough Suppressant
Doxylamine Succinate ……Antihistamine

12 FL OZ (354 mL)
INDEPENDENTLY TESTED SATISFACTION GUARANTEED PV

DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING

*This product is not manufactured or distributed by Procter and Gamble, owner of the registered trademark Vicks® NyQuil®

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

DISTRIBUTED BY
CHAN DRUG CONSORTIUM
3301 NW BOCO RATON BLVD
SUITE 101, BOCA RATON FL 33431
LR-024

NIGHT-TIME ORIGINAL MULTI-SYMPTOM COLD/FLU RELIEF

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-144
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 - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg 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:68016-144-00	236 mL in 1 BOTTLE		
2	NDC:68016-144-01	354 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/01/2012	

Labeler - Chain Drug Consortium, LLC (101668460)

Registrant - AptaPharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(68016-144)

Revised: 5/2013 Chain Drug Consortium, LLC