COLD AND FLU NIGHT-TIME MULTI SYMPTOM RELIEF CHERRYacetaminophen, dextromethorphan hbr, doxylamine succinate liquid Pharmacy Value Alliance, LLC

Cold & Flu Night-time Multi Symptom Relief

Drug Facts

Active ingredients (in each 30 mL dose cup)

Acetaminophen 650 mg
Dextromethorphan HBr 30 mg
Doxylamine Succinate 12.5 mg

Purpose

Acetaminophen Pain reliever/fever reducer Dextromethorphan HBr Cough suppressant Doxylamine Succinate Antihistamine

Uses temporarily relieves cold/flu symptoms: • sore throat • headache • minor aches and pain • 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, 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 two 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, 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.

Keep out of reach of children.

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 warning • Use dose cup or tablespoon ([BSP) • 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 30 mL (2 TBSP) years and over every 6 hours

children 4 to ask a doctor

under 12 years

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

Questions? Call weekdays from 9:30 am to 4:30 pm EST. **1:877-798-5944.**

Principal Display Panel

Premier Value®

COMPARE TO THE ACTIVE

INGREDIENTS IN VICKS® NYQUIL®*

COLD & FLU Night-time Multi-Symptom Relief

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

Cherry Flavor

8 FL OZ (237 mL)

INDEPENDENTLY TESTED PV SATISFACTION GUARANTEED

Questions? Call weekdays 1-877-798-5944.

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

DISTRIBUTED BY: PHARMACY VALUE ALLIANCE, LLC 407 EAST LANCASTER AVENUE, WAYNE PA 19087 If for any reason you are not satisfied with this product, please return It to the store where purchased for a full refund.

LR-025 REV 01

Product Label - Cold & Flu Night-time Multi Symptom Relief Cherry - 8 OZ Package





Product Label - Cold & Flu Night-time Multi Symptom Relief Cherry - 12 OZ Package



COLD AND FLU NIGHT-TIME MULTI SYMPTOM RELIEF CHERRY

acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-237	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
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:68016-237- 08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	
2	NDC:68016-237- 12	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/01/2018	

Labeler - Pharmacy Value Alliance, LLC (101668460)

Registrant - AptaPharma Inc. (790523323)

Establishment					
Name	Address	ID/FEI	Business Operations		
AptaPharma Inc.		790523323	manufacture(68016-237)		

Revised: 12/2023 Pharmacy Value Alliance, LLC