COLD AND FLU NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid
QUALITY CHOICE (Chain Drug Marketing Association)

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.

Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Uses

- temporarily relieves these common cold/flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - 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 doses of acetaminophen in 24 hours
- 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 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- 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.
- with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist

Ask a doctor before use if you have
- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that that lasts or occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking
- sedatives or tranquilizers
- the blood thinning drug warfarin

When using this product
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives and tranquilizers may increase drowsiness

Stop use and ask a doctor if
- pain or cough gets worse or lasts more than 7 days
- new symptoms occur
- fever gets worse or lasts more than 7 days
- redness or swelling is present
- 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 (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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
- **do not take more than directed (see Overdose warning)**
- do not take more than 4 doses in any 24-hours period
- measure only with dosing cup provided. Do not use any other dosing device.
- mL= milliliter
- keep dosing cup with product
- adults and children 12 years and over: 30 mL every 6 hours
- children under 12 years of age: do not use
- **When using other Day Time or Night Time products, carefully read each label to ensure**

correct dosing

Other information

- **each 30 mL contains:** potassium 5 mg
- **each 30 mL contains**: Sodium 19 mg
- store between 20-25ºC (68-77ºF). Do not refrigerate.

Inactive ingredients

acesulfame potassium, alcohol, citric acid, D&C yellow #10, FD&C green #3, FD&C yellow #6,, flavor,high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions or comments?

Call **1-248-449-9300 Monday-Friday 9AM-5PM EST**

Principal Display Panel

*Compare to the active ingredients in VICKS® NYQUIL® Cold & Flu

Nighttime Cold & Flu

Acetaminophen

Dextromethorphan

Doxylamine succinate

For Relief of:

Aches | Fever | Cough

Runny Nose & Sneezing

For Ages 12 Years & Over

Alcohol 10 %

Original Flavor

FL OZ (mL)

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TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

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www.qualitychoice.com

Product Label

QUALITY CHOICE Nighttime Cold & Flu

COLD AND FLU NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-140
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**
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-140-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2016	
2	NDC:63868-140-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	03/31/2016	

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

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