COLD AND FLU NIGHTTIME- acetaminophen, dextromethorphan hbr, doxylamine succinate liquid Best Choice (Valu Merchandisers Company)

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 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 lasts or as occurs with smoking, asthma, chronic bronchits, or emphysema
- trouble urinating due to 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 3 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-hour 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 24 mg
- store between 20-25°C (68-77°F). Do not refrigerate

Inactive ingredients

acesulfame potassium, alcohol, citric acid, FD&C blue #1, FD&C red #40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

*Compare to the active ingredients in Vicks® NyQuil® Cold & Flu

Cold & Flu Relief

ACETAMINOPHEN 650 mg, PAIN RELIEVER / FEVER REDUCER

DEXTROMETHORPHAN HBr 30 mg, COUGH SUPPRESSANT

DOXYLAMINE SUCCINATE 12.5 mg, ANTIHISTAMINE

For relief of:

- Cough
- Sneezing & runny nose
- Headache, fever & sore throat
- Minor aches & pains

FL OZ (mL)

FOR AGES 12 YEARS AND OVER

Cherry Flavor

NIGHTTIME

ALCOHOL 10%

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

PROUDLY DISTRIBUTED BY:

ASSOCIATED WHOLESALE GROCERS, INC.

KANSAS CITY, KANSAS 66106

Product Label



BEST CHOICE Cold & Flu Relief Cherry Flavor

COLD AND FLU NIGHTTIME acetaminophen, dextromethorphan hbr, doxylamine succinate liquid Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:63941-343 Route of Administration ORAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	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)		
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)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63941- 343-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/31/2016		
2	NDC:63941- 343-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/31/2016		

Marketing In	arketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M012	10/31/2016			

Labeler - Best Choice (Valu Merchandisers Company) (868703513)