COLD AND FLU RELIEF NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid
Freds Inc

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 doses (8 tablespoons or 120 mL) 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 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)
- breathing problems or chronic cough 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
- redness or swelling is present
- new symptoms occur
- fever gets worse or lasts more than 3 days
- 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
- keep dosing cup with product
- mL= milliliter
- 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 20-25ºC (68-77ºF). 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

Principal Display Panel

NIGHTTIME RELIEF

Cold & Flu

Each dose (per 30 mL) of oral solution contains:

650 mg-Acetaminophen (Pain Reliever/Fever Reducer)

30 mg- Dextromethorphan HBr (Cough Suppressant)

12.5 mg- Doxylamine succinate (Antihistamine)

- Aches, fever & Sore Throat
- Sneezing, Runny Nose
- Cough

Alcohol 10 % • Ages 12+

FL OZ (mL)

Cherry Flavor

Compare to the Active Ingredients in Vicks® Nyquil®*

*This product is not manufactured or distributed by The Procter & Gamble, Vicks® NyQuil® are registered trademarks of The Procter & Gamble Company

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

DISTRIBUTED BY: fred's Inc,

4300 NEW GETWELL RD., MEMPHIS, TN 38118

www.fredsinc.com

Product Label

FRED'S PHARMACY NightTime Cold & Flu Relief

COLD AND FLU RELIEF NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55315-443
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: 3WQ0SDW1A)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-443-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2018	06/30/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/31/2018	06/30/2024

Labeler - Freds Inc (005866116)

Revised: 11/2023 Freds Inc