COLD AND FLU NIGHT- acetaminophen, dextromethorphan hbr, doxylamine succinate solution Walgreen Company

Walgreens 44-013

Active ingredients (in each 30 mL)

Acetaminophen 650 mg Dextromethorphan HBr 30 mg Doxylamine succinate 12.5 mg

Purpose

Pain reliever/fever reducer Cough suppressant Antihistamine

Uses

- temporarily relieves common cold and flu symptoms:
 - runny nose and sneezing
 - sore throat
 - headache
 - minor aches and pains
 - cough due to minor throat and bronchial irritation
- temporarily reduces fever

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
- 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

- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- difficulty in urination due to enlargement of the prostate gland
- 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
- liver disease
- glaucoma

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- excitability may occur, especially in children
- avoid alcoholic beverages
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- pain or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- 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.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt 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

- do not exceed 4 doses per 24 hours
- mL = milliliter
- only use the dose cup provided
- adults and children 12 years and over: 30 mL every 6 hours
- children under 12 years: do not use

Other information

- each 30 mL contains: sodium 13 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients

anhydrous citric acid, FD&C blue #1, FD&C red #40, flavor, glycerin, high fructose corn syrup, polyethylene glycol 400, propylene glycol, purified water, sodium benzoate, sodium chloride, sodium citrate dihydrate, sodium saccharin, sucralose

Questions or comments?

1-800-426-9391

Principal display panel

NDC 0363-9913-02

Walgreens

WALGREENS PHARMACIST RECOMMENDED[†]

Compare to the active ingredients in Vicks® NyQuil® Cold & Flu^{††}

NIGHT Cold & Flu

ACETAMINOPHEN/

PAIN RELIEVER / FEVER REDUCER DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT DOXYLAMINE SUCCINATE / ANTIHISTAMINE

 Relieves headaches, fever, sore throat, minor aches
 pains, sneezing, cough

- Runny nose
- Ages 12 Years and Over

Cherry flavor

12 FL OZ (355 mL)

TAMPER EVIDENT: DO NOT USE IF PRINTED NECK WRAP IS BROKEN OR MISSING

PARENTS:

Learn about teen medicine abuse www.StopMedicineAbuse.org

Do Not Take Daytime and Nighttime Products at the Same Time.

[†]Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands. ^{††}This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademark Vicks® NyQuil® Cold & Flu.

DISTRIBUTED BY: WALGREEN CO. 200 WILMOT RD., DEERFIELD, IL 60015 100% SATISFACTION GUARANTEED walgreens.com ©2022 Walgreen Co.

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Questions or comments? 1-800-426-9391

Walgreens 44-013

COLD AND FLU NIGHT acetaminophen, dextrometh-rphan hbr, doxylamine succinate solution Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:0363-9913

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: WZ B9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	red (maroon)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

	#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:0363- 9913-02	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/14/2022	
	2	NDC:0363- 9913-96	2 in 1 PACKAGE	11/14/2022	
	2	NDC:0363- 9913-02	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
1					

Marketing Information

Marketing

Category	Citation	Date	Date
OTC Monograph Drug	M012	11/14/2022	

Labeler - Walgreen Company (008965063)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	manufacture(0363-9913) , pack(0363-9913)

Revised: 11/2023

Walgreen Company