

NIGHT TIME SEVERE COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl liquid

Walgreen Company

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.

Night Time Severe Cold & Flu

Drug Facts

Active ingredients

(in each 30 mL dose cup or 2 tablespoons)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Doxylamine Succinate 12.5 mg

Phenylephrine HCl 10 mg

Purpose

AcetaminophenPain reliever/Fever reducer

Dextromethorphan HBr.....Cough suppressant

Doxylamine SuccinateAntihistamine

Phenylephrine HClNasal decongestant

Uses Temporarily relieves cold/flu symptoms: ■ nasal congestion ■ sinus congestion & pressure ■ sore throat ■ headache ■ minor aches and pain ■ runny nose and sneezing ■ temporarily reduces fever ■ cough due to minor throat and bronchial irritation ■ promotes nasal and/or sinus drainage

Warnings **Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 4 doses in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks daily 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 ■ to make a child sleep.

Ask a doctor before use if you have ■ a sodium restricted diet. liver disease ■ heart disease ■ glaucoma ■ high blood pressure ■ thyroid disease ■ diabetes. 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 of pharmacist before use if you are ■ taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin.

When using this product ■ do not use more than directed ■ avoid alcoholic drinks ■ marked drowsiness may occur ■ excitability may occur, especially in children, ■ be careful when driving a motor vehicle or operating machinery ■ alcohol, sedatives, and tranquilizers may increase drowsiness.

Stop use and ask a doctor if ■ you get nervous, *dizzy or sleepless* ■ *redness* or swelling is present ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ 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. 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 Warnings
- use dose cup or tablespoon (TBSP)
- do not exceed 4 doses per 24 hours

Age	Dose
Adults & children 12 years & over	30 mL (2 TBSP) every 4 hours
Children 4 to under 12 years	Ask a doctor
Children under 4 years	Do not use

- do not exceed 4 doses per 24 hours

Other information

- each 30 mL contains: **sodium 45 mg**
- store at room temperature

Inactive ingredients anhydrous citric acid, dextrose, D&C Yellow # 10, FD&C Green # 3, FD&C Yellow # 6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sorbitol, xanthan gum

Questions? Call weekdays from 9:30 AM to 4:30 PM EST at **1-877-798-5944**.

Product Label

Walgreens

*Compare to Vicks® NyQuil™
Severe Nighttime Cold &
Flu Relief active ingredients††*

NDC 0363-0331-26

NIGHTTIME

Severe Cold & Flu

**ACETAMINOPHEN / FEVER REDUCER
DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT
DOXYLAMINE SUCCINATE / ANTIHISTAMINE
PHENYLPHRINE HCl / NASAL DECONGESTANT**

AMAXIMUM STRENGTH

- **Pain reliever, fever reducer,
cough suppressant, antihistamine
& nasal decongestant**

ORIGINAL

FLAVOR

8 FL OZ (237 mL)

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR TORN

DISTRIBUTED BY WALGREEN CO., 200 WILMONT RD., DEERFIELD, IL 60015

100 % SATISFACTION GUARANTEED walgreens.com@2020WalgreenVo.

LR-151

ORG1020-F

Walgreens

Compare to Vicks[®] NyQuil[™] Severe Nighttime Cold & Flu Relief active ingredients^{††}

NDC 0363-0331-26

NIGHTTIME

Severe Cold & Flu

ACETAMINOPHEN / FEVER REDUCER
DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT
DOXYLAMINE SUCCINATE / ANTIHISTAMINE
PHENYLEPHRINE HCl / NASAL DECONGESTANT

MAXIMUM STRENGTH

- Pain reliever, fever reducer, cough suppressant, antihistamine & nasal decongestant

ORIGINAL FLAVOR

8 FL OZ (237 mL)

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN

Drug Facts

Active ingredients (in each 30 mL dose cup or 2 tablespoons)	Purpose
Acetaminophen 650 mg	Pain reliever/Fever reducer
Dextromethorphan HBr 20 mg	Cough suppressant
Doxylamine Succinate 12.5 mg	Antihistamine
Phenylephrine HCl 10 mg	Nasal decongestant

Uses Temporarily relieves cold/flu symptoms: ■ nasal congestion ■ sinus congestion & pressure ■ sore throat ■ headache ■ minor aches and pain ■ runny nose and sneezing ■ temporarily reduces fever ■ cough due to minor throat and bronchial irritation ■ promotes nasal and/or sinus drainage

Warnings **Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 4 doses in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks daily 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

Drug Facts (cont'd)

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 sleep.

Ask a doctor before use if you have ■ a sodium restricted diet ■ liver disease ■ heart disease ■ glaucoma ■ high blood pressure ■ thyroid disease ■ diabetes ■ 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.

DISTRIBUTED BY: WALGREEN CO., 200 W. MONT RD., DEERFIELD, IL 60015
100% SATISFACTION GUARANTEED walgreens.com ©2020 Walgreen Co.

LR-151

ITEM 268847 W10139-1120-F



ORG1020-F

Drug Facts (cont'd)

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

When using this product ■ do not use more than directed ■ avoid alcoholic drinks ■ marked drowsiness may occur ■ excitability may occur, especially in children, ■ be careful when driving a motor vehicle or operating machinery ■ alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if ■ you get nervous, dizzy or sleepless ■ redness or swelling is present ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ 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. 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 Warnings
- use dose cup or teaspoon (TBS)
- do not exceed 4 doses per 24 hours

Age	Dose
Adults & children 12 years and over	30 mL (2 TBS) every 4 hours
Children 4 to under 12 years	Ask a doctor
Children under 4 years	Do not use

Other Information

- each 30 mL contains: sodium 46 mg
- store at room temperature

Inactive ingredients anhydrous citric acid, D&C Yellow # 10, FD&C Green # 3, FD&C Yellow # 6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sorbitol, xanthan gum

Questions? Call weekdays from 9:30 AM to 4:30 PM EST at 1-877-798-6944

Walgreens Pharmacist Recommended
Procter & Gamble, owner of the registered trademark Vicks[®] NyQuil[™] Severe.

RES

NIGHT TIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0331
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	20 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	10 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	green (Original Cough Syrup Flavor)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0331-26	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/13/2020	

Labeler - Walgreen Company (008965063)**Registrant** - AptaPharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(0363-0331)

Revised: 12/2020

Walgreen Company