

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

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

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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.

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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 (TBSF)
- do not exceed 4 doses per 24 hours

Age	Dose
Adults & children 12 years and over	30 mL (2 TBSF) 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.

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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 Drug	M012	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: 12/2023

Walgreen Company