NIGHTTIME SEVERE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride solution Walgreen Company

Walgreen Co. Nighttime Severe Cold & Flu Drug Facts

Active ingredients (in each 15 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine Succinate 6.25 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- cough to help you sleep
- minor aches and pains
- headache
- sore throat
- fever
- runny nose and sneezing
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours

- taken with other drugs containing acetaminophen
- adult has 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
- to make a child sleepy

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- glaucoma
- thyroid disease
- diabetes
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are

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

When using this product

- do not use more than directed
- 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

- you get nervous, dizzy or sleepless
- pain, nasal congestion, or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- 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.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 directed see Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 4 hrs
children 6 to under 12 yrs	15 mL every 4 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- each 15 mL contains: sodium 15 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

anhydrous citric acid, D&C yellow #10, edetate disodium, FD&C green #3, FD&C red #40, FD&C yellow #6, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose, xanthan gum

Questions?

1-800-719-9260

Package/Label Principal Display Panel

Walgreens

WALGREENS PHARMACIST RECOMMENDED

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

NIGHTTIME Severe Cold & Flu

ACETAMINOPHEN / PAIN RELIEVER / FEVER REDUCER

PHENYLEPHRINE HCI / NASAL DECONGESTANT

DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT

DOXYLAMINE SUCCINATE / ANTIHISTAMINE

Maximum Strength

- Headache, fever, sore throat, minor aches & pains
- Nasal/sinus congestion, sinus pressure
- Sneezing & runny nose
- Cough Cold & flu

Honey flavor

12 FL OZ (355 mL)

NDC 0363-2029-40

Walgreens

Compare to the active ingredients in Vicks® NyQuil® Severe Cold & Flu^H



NIGHTTIME

Severe Cold & Flu

ACETAMINOPHEN / PAIN RELIEVER / FEVER REDUCER PHENYLEPHRINE HCI / NASAL DECONGESTANT DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT DOXYLAMINE SUCCINATE / ANTIHISTAMINE

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Honey flavor

12 FL OZ (355 mL)

: 86240 94 Fl

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PARENTS:

ITEM 714663 W10107-0623-F REV-0323

www.StopMedicineAbuse.org

Drug Facts

Active ingredients (in each 15 mL)

Pain reliever/

Purpose

325 mg...... Dextromethorphan HBr

Acetaminophen

10 mg......Cough suppressant Doxylamine Succinate 6.25 mg...Anthistamine Phenylephrine HOI 5 mg...Nasal decongestant

Uses temporarily relieves common cold/flu symptoms: ■ nasal congestion ■ sinus congestion and pressure ■ cough due to minor throat and bronchial irritation ■ cough

to help you sleep ■ minor aches and pains ■ headache ■ sore throat ■ fever ■ runny nose and sneezing

■ reduces swelling of nasal passages ■ temporarily restores freer breathing through the nose ■ promotes nasal and/or sinus drainage

Warnings

Liver warning: This product contains acetaminophen.

Severe liver damage may occur if adult takes more than 4,000 mg of acetaminophen in 24 hours child takes more than 5 doses in 24 hours taken with other drugs containing acetaminophen adult has 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

■ 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.

PEEL BACK AT CORNER FOR MORE INFORMATION

: 4FZ40 44 B5

Drug Facts (continued)

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 I to make a child sleepy Ask a doctor before use if you have

■ liver disease ■ heart disease
■ high blood pressure ■ glaucoma.

■ thyroid disease ■ diabetes

cough that occurs with too much

Drug Facts (continued)

■ avoid alcoholic drinks ■ be careful when driving a motor vehicle or operating machinery ■ alcohol, sedatives, and tranquilizers may increase wriness

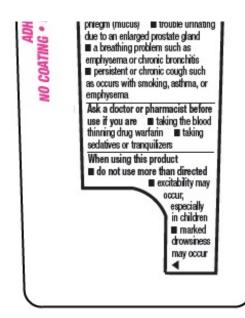
Stop use and ask a doctor if ■ you get nervous, dizzy or sleepless ■ pain, nasal congestion, or cough gets worse or lasts more than 5 days (children) or 7 days (adults) ■ fever gets worse or lasts more than 3 days ■ recliness or swelling is present ■ new symptoms occur ■ cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

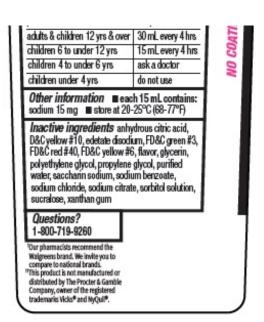
If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 directed - see Overdose warning ■ only use the dose cup provided ■ do not exceed 4 doses per 24 hrs • NO VARNISH • NO TYPE

ESIVE AREA No varnish • no type





NIGHTTIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-2029
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg in 15 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL	
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg in 15 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		

WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-2029- 40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/08/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/08/2023	

Labeler - Walgreen Company (008965063)

Revised: 11/2024 Walgreen Company