

**WALGREEN NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and phenylephrine hydrochloride solution
WALGREENS CO.**

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.

Walgreens Nighttime Cold & Flu Relief

Drug Facts

Active ingredients (in each 15 mL)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Doxylamine succinate 6.25 mg
Phenylephrine HCl 5 mg

Pain reliever/fever reducer
Cough suppressant
Antihistamine
Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- cough to help you sleep
- minor aches & pains
- headache
- fever
- sore throat
- runny nose & 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

- adults take more than 4 doses (30mL each) in 24 hours, which is the maximum daily amount for this product

- taken with other drugs containing acetaminophen
- adults 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.
- to make child sleepy

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- 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 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**
- 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.

In case of overdose, get medical help or contact a Poison Control Center right away at 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
- 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	do not use unless directed by a doctor
children under 4 years	Do not use

Other information

- **each 15 mL contains:** sodium 9 mg
- Store at room temperature.
- Do not refrigerate.

Inactive ingredients

citric acid, D&C Yellow No. 10, disodium edetate, FD&C Green No. 3, FD&C Red No. 40, flavors, glycerin, menthol, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum.

Questions?

1-866-467-2748

Distributed by:

PRINCIPAL DISPLAY PANEL - 354mL Bottle Label

*Compare to the active ingredients in VICKS® NyQuil™ Severe Cold & Flu Honey Flavor

NDC 0363-6111-12

Nighttime Cold & Flu

Relief

Acetaminophen- Pain reliever/Fever reducer

Phenylephrine HCl - Nasal decongestant

Doxylamine Succinate - Antihistamine

Dextromethorphan HBr - Cough suppressant

- Headache, Fever, Sore Throat,
Minor Aches & Pains
- Nasal Congestion & Sinus Pressure
- Sneezing, Runny Nose
- Cough

Honey Flavor

Naturally and Artificially Flavored

12 FL OZ (354 ml)

<p>Drug Facts (continued)</p> <p>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</p> <p>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.</p> <p>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 at 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.</p> <p>Directions • take only as directed • 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 do not use unless directed by a doctor children under 4 yrs do not use</p> <p>Other information • each 15 mL contains: sodium 9 mg • store at room temperature. Do not refrigerate.</p> <p>Inactive ingredients citric acid, D&C Yellow No. 10, edetate disodium, FD&C Green No. 3, FD&C Red No. 40, flavors, glycerin, menthol, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum.</p> <p>Questions or comments? 1-866-467-2748</p>	<p>*Compare to the active ingredients in Vicks® NyQuil™ Severe Cold & Flu Honey Flavor NDC 0363-6111-12</p> <h1>Nighttime Cold & Flu Relief</h1> <p>Acetaminophen - Pain reliever/Fever reducer Phenylephrine HCl - Nasal decongestant Doxylamine succinate - Antihistamine Dextromethorphan HBr - Cough suppressant</p> <ul style="list-style-type: none">• Headache, Fever, Sore Throat, Minor Aches & Pains• Nasal Congestion, Sinus Pressure• Sneezing, Runny Nose• Cough <p>Honey Flavor Naturally and Artificially Flavored 12 FL OZ (354 ml)</p>	<p>Drug Facts DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN</p> <table border="1"><thead><tr><th>Active ingredients (in each 15 mL)</th><th>Purpose</th></tr></thead><tbody><tr><td>Acetaminophen 325 mg</td><td>Pain reliever/fever reducer</td></tr><tr><td>Dextromethorphan HBr 10 mg</td><td>Cough suppressant</td></tr><tr><td>Doxylamine succinate 6.25 mg</td><td>Antihistamine</td></tr><tr><td>Phenylephrine HCl 5 mg</td><td>Nasal decongestant</td></tr></tbody></table> <p>Uses temporarily relieves common cold/flu symptoms • nasal congestion • sinus congestion & pressure • cough due to minor throat & bronchial irritation • cough to help you sleep • minor aches & pains • headache • fever • sore throat • runny nose & sneezing • reduces swelling of nasal passages • temporarily restores freer breathing through the nose • promotes nasal and/or sinus drainage</p> <p>Warnings Liver warning: This product contains acetaminophen. Severe liver damage may occur if • adult takes more than 4 doses (30 mL each) in 24 hrs, which is the maximum daily amount for this product • child takes more than 4 doses (15 mL each) in 24 hrs, which is the maximum daily amount for this product • 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.</p> <p>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 sleepy</p> <p>Ask a doctor before use if you have • liver disease • heart disease • high blood pressure • thyroid disease • diabetes • glaucoma • 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 an enlarged prostate gland</p> <p>Ask a doctor or pharmacist before use if you are • taking sedatives or tranquilizers • taking the blood thinning drug warfarin</p>	Active ingredients (in each 15 mL)	Purpose	Acetaminophen 325 mg	Pain reliever/fever reducer	Dextromethorphan HBr 10 mg	Cough suppressant	Doxylamine succinate 6.25 mg	Antihistamine	Phenylephrine HCl 5 mg	Nasal decongestant
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Non - Varnish Area

WALGREEN NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and phenylephrine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-6111
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
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)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	BROWN	Score	
Shape		Size	
Flavor	HONEY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-6111-12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/11/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/11/2021	

Labeler - WALGREENS CO. (008965063)

Revised: 2/2021

WALGREENS CO.