# SEVERE COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl 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.

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#### Walgreen Co. Daytime / Nighttime Severe Cold & Flu Drug Facts

#### Nighttime Severe Cold & Flu Active ingredients (in each 30 mL)

Acetaminophen 650 mg
Dextromethorphan HBr 20 mg
Doxylamine succinate 12.5 mg
Phenylephrine HCl 10 mg

#### **Purpose**

Pain reliever/fever reducer
Cough suppressant
Antihistamine
Nasal decongestant

#### Uses

temporarily relieves common cold/flu symptoms:

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

## 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

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

# 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 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.

**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 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

#### Other information

- each 30 mL contains: sodium 41 mg
- store at 20-25°C (68-77°F)

## **Inactive ingredients**

anhydrous citric acid, edetate disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose, xanthan gum

#### **Questions or comments?**

#### 1-800-719-9260

### Daytime Severe Cold & Flu Active ingredients (in each 15 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCI 5 mg

#### **Purpose**

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

#### Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- minor aches and pains
- headache
- fever
- sore throat
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- · promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

## **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

#### Ask a doctor before use if you have

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

### Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

# When using this product do not use more than directed

#### 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 care 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 6 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

# **Inactive ingredients**

butylated hydroxyanisole, edetate disodium, FD&C yellow #6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

#### Questions or comments?

1-800-719-9260

# **Principal Display Panel**

**DAY & NIGHT PACK** 

Walgreens

WALGREENS PHARMACIST RECOMMENDED

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

NyQuil® Severe Cold & Flu

DAYTIME

**NON-DROWSY** 

Severe Cold & Flu

ACETAMINOPHEN / ACHES / FEVER / SORE THROAT

DEXTROMETHORPHAN HBr / COUGH

**GUAIFENESIN / CHEST CONGESTION** 

PHENYLEPHRINE HCI / NASAL CONGESTION

Maximum Strength

- Pain reliever, fever reducer, cough suppressant, expectorant & nasal decongestant
- Antihistamine free
- Alcohol free

NIGHTTIME

Severe Cold & Flu

ACETAMINOPHEN / ACHES / FEVER / SORE THROAT

DEXTROMETHORPHAN HBr / COUGH

DOXYLAMINE SUCCINATE / SNEEZING / RUNNY NOSE

PHENYLEPRHINE HCI / NASAL & SINUS CONGESTION / SINUS PRESSURE

Maximum Strength

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

Mixed Berry flavor

2 - 12 FL OZ (355 mL) BOTTLES / TOTAL 24 FL OZ (1.5 pt) (710 mL)



DAY & NIGHT PACK

NDC 0363-1597-02

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

# Walgreens





DAYTIME NON-DROWSY

# Severe Cold & Flu

ACETAMINOPHEN / ACHES / FEVER / SORE THROAT DEXTROMETHORPHAN HBr / COUGH GUAIFENESIN / CHEST CONGESTION PHENYLEPHRINE HCI / NASAL CONGESTION

#### Maximum Strength

- Pain reliever, fever reducer, cough suppressant, expectorant & nasal decongestant
- · Antihistamine free
- Alcohol free

**NIGHTTIME** 

# Severe Cold & Flu

ACETAMINOPHEN / ACHES /
FEVER / SORE THROAT
DEXTROMETHORPHAN HBr / COUGH
DOXYLAMINE SUCCINATE /
SNEEZING / RUNNY NOSE
PHENYLEPHRINE HCI /
NASAL & SINUS CONGESTION /
SINUS PRESSURE

#### Maximum Strength

- Pain reliever, fever reducer, cough suppressant, antihistamine
   anasal decongestant
- · Alcohol free

Mixed Berry flavor

2 - 12 FL 0Z (355 mL) BOTTLES / TOTAL 24 FL 0Z (1.5 pt) (710 mL)

Gluten Free



# PARENTS: Learn about teen medicine abuse

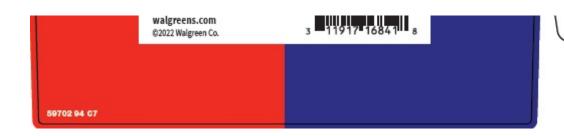
www.StopMedicineAbuse.org

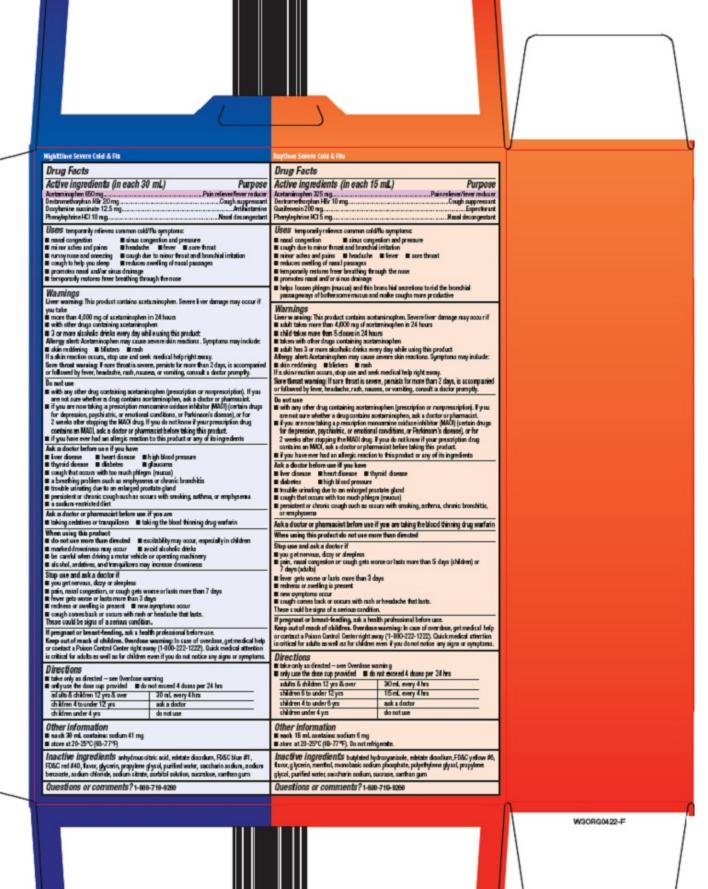
\*\*Our pharmacists recommend the Waigreens brand. We invite you to compare to national brands. 
\*\*These products are not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademarks Vicks\*\* NyQuil\*\* and DayQuil\*.

DISTRIBUTED BY: WALGREEN CO. 200 WILMOT RD., DEERFIELD, IL 60015

100% SATISFACTION GUARANTEED







### **SEVERE COLD AND FLU**

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0363-1597

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:0363-1597- 02	1 in 1 CARTON; Type 0: Not a Combination Product	09/08/2014	

Quantity of Parts			
Part #	Package Quantity	Total Product Quantity	
Part 1	1 BOTTLE	355 mL	
Part 2	1 BOTTLE	355 ml	

### Part 1 of 2

#### **SEVERE COLD AND FLU**

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl solution

<b>Product Information</b>	
Item Code (Source)	NDC:0363-0763
Route of Administration	ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 30 mL	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (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 HYDROCHLORIDE	10 mg in 30 mL	

#### **Inactive Ingredients**

Strength

Product Characteristics			
Color	RED (clear, dark)	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:0363-0763- 40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/21/2013	

# Part 2 of 2

# **SEVERE COLD AND FLU**

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

<b>Product Information</b>	
Item Code (Source)	NDC:0363-0603
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	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL	

Inactive Ingredients	
Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	ORANGE (clear)	Score	
Shape		Size	
Flavor	FRUIT, MENTHOL	Imprint Code	
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:0363-0603- 40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/21/2013	

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/08/2014	

# Labeler - Walgreen Company (008965063)

Revised: 9/2022 Walgreen Company