# BASIC CARE DAYTIME SEVERE COLD AND FLU NIGHTTIME SEVERE COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate, guaifenesin, phenylephrine hcl Amazon.com Services LLC

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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### Amazon Daytime Severe Cold & Flu Nighttime Sever 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 HCl 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**

amazon

basic care

Multi-Symptom Relief

Compare to Vicks® DayQuil® Severe active ingredients

Non-Drowsy

Daytime Severe Cold & Flu

Acetaminophen

Dextromethorphan HBr

Guaifenesin

Phenylephrine HCI

Pain Reliever/Fever Reducer

Nasal Decongestant

Cough Suppressant

Expectorant

ALCOHOL FREE

Max Strength

Original Flavor

Maximum Strength

Compare to Vicks® NyQuil® Severe active ingredients

Nighttime Severe Cold & Flu

Acetaminophen, Phenylephrine HCl, Doxylamine Succinate, Dextromethorphan HBr Pain Reliever, Fever Reducer, Nasal Decongestant, Cough Suppressant, Antihistamine

ALCOHOL FREE

Berry Flavor

**COMBINATION PACK** 

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



basic@care

**Daytime** Severe Cold & Flu

**Nighttime** Severe Cold & Flu



basic@care

Multi-Symptom Relief

Compare to Vicks® DayQuil® Severe

Non-Drowsy

# Daytime Cold & Flu

Acetaminophen Dextromethorphan HBr Guaifenesin Phenylephrine HCI

Pain Reliever/Fever Reducer Nasal Decongestant Expectorant

ALCOHOL FREE Max Strength Maximum

Compare to Vicks NyQuil Severe NDC 72288-597-02 active ingredients

# Nighttime Severe Cold & Flu

Acetaminophen, Phenylephrine HCl. Doxylamine Succinate, Dextromethorphan HBr

Pain Reliever, Fever Reducer, Nasal Decongestant, Cough Suppressant, Antihista mine

ALCOHOL FREE



Original Flavor

# COMBINATION PACK

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





## Nighttime Relief

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



DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

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59702 BN C2



#### Nighttime Severe Cold & Flu

# Daytime Severe Cold & Flu

#### Drug Facts Active ingredients (in each 30 mL) Purpose Dextromethorphan HBr 20 mg.... ...Cough suppressan .....Antihistamin ...Nasal decongestan Doxylamine succinate 12.5 mg.. Phenylephrine HCl 10 mg.....

Uses temporarily relieves common coldflu symptoms:

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- messal congestion mesinus congestion and pressure minor schee and pains meadache fewer mesore throat

- nunny nose and sneezing cough due to minor threat and bronchial imbation
   cough to help you skeep reduces swelling of nasal passages
   promotes rasel and/or situs obtainage
   temporarily restores free breathing through the nose

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you take — more than 4,000 mg of acetaminophen in 24 hours — with other drugs containing acetaminophen — 30 or more skholis denink every day while using this product Allergy alert. Acetaminophen may cause severe akin ne

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  If you have even had an allergic reaction to this product or any of its ingredients.

- Ask a doctor before use if you have

  for disease | heart disease | high blood pressure

  for disease | heart disease | significant |

  thyrid disease | disease | significant |

  cough that occurs with to much phispin (mucu)

  a breathing problem such as emphysema or chronic bronchitis

  trouble unstaing due to an entarged prostate glandking, settline, or emphysema

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  a social muchical dist ■ persistent or chronic cou ■ a sodium-restricted diet

Ask a doctor or pharmacist before use if you are
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- When using this product

  do not use more than directed a excitability may occur, especially in children

  marked drowsiness may occur a sovial disobolic drinks

  be careful when driving a mother which or operating machinery

  alochol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

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#### Directions

only as directed - see Overdose warning

monly use the dose cup provided mode not exceed 4 doces 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 scid, edetate disodium, FD&C blue 41, FD&C red 440, flavor, glycein, propylene glycol, purified water, saccharin sodium, sodiu be recate, sodium chloride, sodium citrate, sorbibol solution, sucralese, santhan gum

Questions or comments? 1-800-719-9260

#### Drug Facts

Active ingredients (in each 15 mL) Purpose Acetaminopheri 325 mg. Dextromethorphan HBr 10 mg. ..Cough suppressa Guaifenesin 200 mg..... Phenylephrine HC45 mg. 

- Uses temporarily referee common cold/flu symptoms:

  nasal congestion sinus congestion and pressure
  cough due to minor throat and bronchial imitation

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for followed by forew headphs in the neuron or womition promists doctor mannels. or followed by fever, headache, rash, nauses, or vomitting, consult a doctor promptly.

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  If you have ever had an allegic reaction to this product or any of its in gradients

- Ask a doctor before use if you have

  fiver classes heart disease thyroid disease
  clasetes high blood pressure
  trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phiegm (musus)
   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

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#### Directions

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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 informs tion

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, n, m enthol, monobe glycol, purified water, saccharin sodium, sucrose, xanthan gum

Questions or comments? 1-800-719-9260

# Daytime Relief

Headache, Fever, Sore Throat. Minor Aches & Pains, Nasal/Sinus Congestion & Sinus Pressure.



\*These products are not manufactured or distributed by Procter & Gamble, distributor of Vicks® DayQuil® Severe and Vicks® NyQuil® Severe

**GLUTEN FREE** 

# PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org





acetaminophen, dextromethorphan hbr, doxylamine succinate, guaifenesin, phenylephrine hcl kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72288-597

#### **Packaging**

ı		: <del></del>			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:72288-597- 02	1 in 1 CARTON; Type 0: Not a Combination Product	03/11/2021	

#### **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

#### **BASIC CARE NIGHTTIME SEVERE COLD AND FLU**

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride solution

#### **Product Information**

Item Code (Source)	NDC:72288-639
Route of Administration	ORAL

#### **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength 650 ma ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN in 30 mL **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) **DEXTROMETHORPHAN** 20 mg (DEXTROMETHORPHAN - UNII:7355X3ROTS) **HYDROBROMIDE** in 30 mL DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE -12.5 mg DOXYLAMINE SUCCINATE UNII:95QB77JKPL) in 30 mL PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -PHENYLEPHRINE 10 mg UNII:1WS297W6MV) **HYDROCHLORIDE** in 30 mL

Inactive Ingredients				
Ingredient Name	Strength			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GLYCERIN (UNII: PDC6A3C0OX)				
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)				

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

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1		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		

# Part 2 of 2

# **BASIC CARE DAYTIME SEVERE COLD AND FLU**

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution

Item Code (Source) NDC:72288-603

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)	

<b>Product Characteris</b>	stics	
Color	ORANGE (clear)	Score
Shape		Size
Flavor	FRUIT, MENTHOL	Imprint Code
Contains		

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:72288-603- 40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
part341			
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/11/2021	

**Labeler -** Amazon.com Services LLC (128990418)

Revised: 11/2022 Amazon.com Services LLC