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.

Amazon Daytime Severe Cold & Flu Nighttime 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 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	30 mL every 4 hrs
yrs & over	
children 4 to under 12	ask a doctor
yrs	
children under 4 yrs	do not use

Other information

- each 30 mL contains: sodium 44 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

alcohol, anhydrous citric acid, D&C yellow #10, edetate disodium, FD&C green #3, FD&C

yellow #6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose

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
- 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
- diabetes

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 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 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

Package/Label 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 HC1

Pain Reliever/Fever Reducer

Nasal Decongestant

Cough Suppressant

Expectorant

Max Strength

ALCOHOL FREE

Original Flavor

Multi-Symptom Relief

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

Max Strength

ALCOHOL 10%

Original 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



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Multi-Symptom

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

Max Strength

ALCOHOL FREE

Multi-Symptom Relief

NDC 72288-804-02

Compare to Vickse NyQuile Severe active ingredients

Nighttime Severe Cold & Flu

Acetaminophen, Phenylephrine HCI, Doxylamine Succinate, Dextromethorphan HBr

Pain Reliever, Fever Reducer, Nasal Decongestant, Cough Suppressant, Antihistamine

Max Strength

ALCOHOL 10%

Original Flavor 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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8G002 BN C2



Nighttime Severe Cold & Flu

Daytime Severe Cold & Flu

Drug Facts

Active ingredients (in each 30 mL)	Purpose
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg	
Dowlamine succinate 12.5 mg.	Antihistamine
Phenylephrine HCl 10 mg	

- Uses temporarily releves common cold/flu symptoms:

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Warnings

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m more than 4,000 mg of acetaminophen in 24 hours

■ with other drugs containing acetambophen ■ 3 or more alcoholic drikks every day willle using this product Allergy alert Acetambophen my cause sewere skin reactions. Symptoms may include: ■ skin reddening ■ bilsters ■ rash

■ Aktin 460 ening ■ 0.154879 ■ 1831 Tha skin reaction occurs, stop use and seek medical help right away. See threat warning: If one throat is severe, persists for more than 2 days, is accompanie or foliowed by fewer, headache, rash, nausea, or wornting, consult a doctor promptly.

Do not use with any other drug containing aestaminophen (prescription or noxprescription). If you are not sure whether a drug contains scataminophen, ask a doctor or pharmacist, if you are now taking a prescription monoamine oxidase inhibitor (MADI) (sertain drugs for depression, psychiatric, or endional conditions, or Parkinson's disease), or for 2 weeks after stopping the MADI drug. If you do not know if your prescription drug contains an MADI, ask a doctor or pharmacist before taking this product. If you have ever had an alergic reaction to this product or any of its ingredients sets a doctor before use if two beas.

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 I cough that occurs with too much phiego (musus)
 I a breathing problem such as emphysema or chronic bronchttle
 I brouble unlating due to an entaged prostate gland
 I persistent or chronic cough as occurs with smoking, ashma, or emphysema
 I a sodium-reshied dief

a sodium-restricted diet

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers in taking the blood thinning drug warfarin

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Stop use and ask a doctor If

- scop use and asix a doctor in
 you get nevus, dizzy or sleepless
 pain, nasal congestion, or cough gets worse or lasts more than 7 days
 feet gets worse or lasts more than 3 days
 referes or westling is present in 30 days
 cough comes back or occurs with nash or headache that lasts.

These could be signs of a serious condition.

if pregnant or breast-leeding, ask a health professional before use. Keep out of reach of children, Overdose warning: In case of overdose, get medical help or contact a Polson Control Center right away (1-804-222-1222), Quick medical atlention is official for adults as well as for children even if you do not notice any algos or symptoms.

Directions

■ take only as directed – see Overdose warning ■ only use the dose cup provided ■ do not ex ceed 4 doses per 24 hrs 30 mL every 4 hrs adults & children 12 yrs & over

children 4 to under 12 yrs ask a docto do not use

Other information

m each 30 mL contains: sodium 44 mg m store at 20-25°C (68-77°F)

Inactive ingredients alcohol, anhydrous citric acid, D&C yellow #10, edetats disorbun, FD&C green #3, FD&C yellow #8, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzorie, sodium chloride, sodium citrate, sorbitol

Questions or comments? 1-800-719-9260

Drug Facts

Drug ruoto	200 000
Active ingredients (in each 15 mL)	Purpose
Acetaminophen 325 mg.	Pain reliever/lever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Gualfenasin 200 mg.	
Phenyleoholae HCI 5 ma	Nasal de congestant

- Uses temporarily relieves common cold/flu symptoms
 nasal congestion m sinus congestion and pres m nasal congestion m shus congestion and pressure cough due to minor throat and bronchial inflation
- mmhor softes and pains me headache metever me sore throat mediaces swelling of nasal passages me 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

- Waitmings

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

 adult takes more than 4,000 mg of acetaminophen in 24 hours

- with any other drug containing scelarningthen prescription or nonprescription). If you are not sure whether a drug contains scartaminophen, ask a doctor or pharmacist, if you are now taking a prescription monoamine oddase inhibitor (MAO) (scartan drugs for depression, psychiatric, or emotional conditions, or Parkhaori's disease), or true. 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 mild you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use If you have

- m persisient or chronic cough such as occurs with smolding, 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 m 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, Oxerdose warring; in case of oxerdose, get medical help or contract a Polonic Control Center (right wavey) (1-00-222-1222). Qubic medical attention is critical for adults as well as for children even if you do not notice any algos or symptoms.

Directions

■ take only as directed – see Overdose warning ■ only use the dose cup provided ■ do not exceed 4 doses per 24 hrs

adulfs & 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 vrs	do not use

Other information

■ each 15 mL contains: sodium 6 mg ■ store at 20-25°C (68-77°F). Do not retrigerate

Inactive ingredients tutyered hydroxyenkole, edetate disodiun, FO&C yellow at flevor, glycerin, menthol, monobasic sodiun phosphate, polyethylene glycol, propylene glycol, purtled water, saccharin sodium, sucrose, xanthan gum

Questions or comments? 1-800-719-9260

Daytime Relief

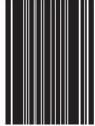
Headache, Fever, & Sinus Pressure,



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

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:72288-804

Packaging

ı				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:72288-804-	1 in 1 CARTON; Type 0: Not a Combination Product	05/13/2021	

Ouantity 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:72288-189
Route of Administration	ORAL

Active Ingredient/Active Moiety Basis of Strength Ingredient Name Strength 650 mg 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 10 mg PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -UNII:1WS297W6MV) **HYDROCHLORIDE** in 30 mL

Inactive Ingredients	
Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
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 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)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	GREEN	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

l	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		NDC:72288-189- 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			

Part 2 of 2

BASIC CARE DAYTIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution

Product Information

	Item Code (Source)	NDC:72288-603
l	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		
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				

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

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

OTC monograph final	part341				
Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part341	05/13/2021			

Labeler - Amazon.com Services LLC (128990418)

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