BASIC CARE NIGHTTIME SEVERE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride solution 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 Nighttime Severe Cold & Flu Drug Facts

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 yrs & over	30 mL every 4 hrs
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

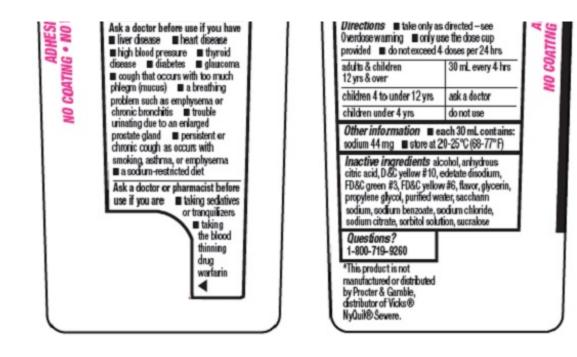
Questions?

1-800-719-9260

Package/Label Principal Display Panel

amazon basic care Multi-Symptom Relief Compare to Vicks[®] NyQuil[®] Severe active ingredients Nightttime Severe Cold & Flu Acetaminophen, Phenylephrine HCl, Doxylamine Succinate, Dextromethorphan HBr Pain Reliever, Fever Reducer, Nasal Decongestant, Cough Suppressant, Antihistamine ALCOHOL 10% Original Flavor Max Strength 12 FL OZ (355 mL)





BASIC CARE NIGHTTIME SEVERE COLD AND FLU acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride solution **Product Information Product Type** HUMAN OTC DRUG 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 HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -PHENYLEPHRINE 10 mg 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: 3P3ONR601S)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

WATER (UNII: 059QF	0KO0R)				
SACCHARIN SODIU		UX40TY)			
SODIUM BENZOATE	UNII: 0J245F	E5EU)			
SODIUM CHLORIDE	(UNII: 451W47	IQ8X)			
SODIUM CITRATE, U	JNSPECIFIED	FORM (UNII: 1Q73Q2J	ULR)		
SORBITOL (UNII: 506					
SUCRALOSE (UNII: 9	6K6UQ3ZD4)				
Product Charae	cteristics				
Color	or GREEN Score				
Shape			Size		
Flavor		MINT	Imprint Code		
Contains					
Deckersing					
Packaging					
# Item Code	Package Description			Marketing Start Date	Marketing End Date
1 NDC:72288-189- 40 Product 355 mL in 1 BOTTLE; Type 0: Not a Combination Product 01/21/2022					
Marketing I	nformat	ion			
Marketing Category	Applica	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part341		01/21/2022		
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