

BASIC CARE NIGHTTIME SEVERE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride tablet, film coated
Amazon.com Services LLC

Amazon Nighttime Severe Cold & Flu Drug Facts

Active ingredients (in each caplet)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

- temporarily relieves common cold/flu symptoms:
- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- cough to help you sleep
- minor aches and pains
- headache
- fever
- sore throat
- runny nose and 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 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
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- trouble urinating due to an 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 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
- do not exceed 8 caplets per 24 hrs

adults & children 12 yrs & over	2 caplets with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Inactive ingredients

crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, FD&C yellow #6 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, silicon dioxide, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Nighttime Relief

Compare to Vicks® NyQuil® Severe+ VapoCOOL™

active ingredients

Nighttime Severe Cold & Flu

Acetaminophen, Phenylephrine HCl, Doxylamine Succinate, Dextromethorphan HBr

actual size

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

Max Strength

Vapor Ice™

24 CAPLETS



Drug Facts

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

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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 ■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema ■ trouble urinating due to an enlarged prostate gland

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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.

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72288-721
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	Strength
CROSPVIDONE (120 .MU.M) (UNII: 68401960MK)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	GREEN	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	L72V
Contains			

Packaging			
		Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72288-721-62	12 in 1 CARTON	12/10/2020	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/10/2020	

Labeler - Amazon.com Services LLC (128990418)

Revised: 11/2024

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