## BASIC CARE NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled 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 Nighttime Cold & Flu Drug Facts

#### Active ingredients (in each softgel)

Acetaminophen 325 mg
Dextromethorphan HBr 15 mg
Doxylamine succinate 6.25 mg

#### **Purpose**

Pain reliever/fever reducer
Cough suppressant
Antihistamine

#### Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

#### **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, lasts 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
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- · persistent or chronic cough 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

- 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

- pain 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 4 doses per 24 hours

adults & children 12 yrs & over	2 softgels with water every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

#### Other information

store at 20-25°C (68-77°F)

#### **Inactive ingredients**

D&C yellow no. 10, edible ink\*, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution \*may contain this ingredient

#### Questions or comments?

1-800-719-9260

#### Package/Label Principal Display Panel

Multi-Symptom Relief

Compare to Vicks® NyQuil® Cold & Flu active ingredients

Nighttime Cold & Flu

Acetaminophen, Dextromethorphan HBr

Doxylamine Succinate

Pain Reliever/Fever Reducer, Antihistamine

Cough Suppressant

Alcohol Free

actual size





#### CONVENIENT RECLOSING TAB

Drug Facts

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

Active ingredients (in each softgel)

Purpose

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..Pain reliever/fever reducer

Dextromethorphan HBr 15 mg......Cough suppressant

Doxylamine succinate 6.25 mg.....

.....Antihistamine

Uses temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- runny nose and sneezing
   sore throat
- minor aches and pains ■ headache
  ■ fever

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- with other drugs containing acetaminophen
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- skin reddening blisters rash
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■ taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin

When using this product excitability may occur, especially in children

- be careful when driving a motor vehicle or operating machinery avoid alcoholic drinks
  - marked drowsiness may occur
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- Stop use and ask a doctor if pain or cough gets worse or lasts more than 7 days

- redness or swelling is present fever gets worse or lasts more than 3 days 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.

# *Drug Facts* (continued)

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■ take only as directed —see overdose warning	adults & children 12 yrs & over	children 4 to under 1 2 yrs	children un der 4 yrs

www.StopMedicineAbuse.org

per 24 hours

55

\*\*This product is not manufactured

or distributed by Procter & Gamble distributor of Vicks® NyQui(®

Gluten Free

Cold & Flu

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Inactive ingredients D&C yellowno.10, edible inkt, FD&C blue no.1, gelatin, glycerin polyathylene glycol, povid one, propylane glycol, purified water, sorbit al sorbitan solution maycontain this ingredient

Questions or comments ?1-8 00-71 9-926 0

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

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72288-056
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg		
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg		

Inactive Ingredients			
Ingredient Name	Strength		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
SORBITAN (UNII: 6092ICV9RU)			

Product Characteristics				
Color	GREEN (clear)	Score	no score	
Shape	OVAL	Size	20mm	
Flavor		Imprint Code	056	
Contains				

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:72288-056- 67	24 in 1 CARTON	12/28/2020	

1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:72288-056- 62	12 in 1 CARTON	09/07/2021	
2		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 final	part341	12/28/2020	

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

Revised: 9/2021 Amazon.com Services LLC