BASIC CARE DAYTIME COLD AND FLU- acetaminophen, dextromethorphan hbr, phenylephrine hcl 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 Daytime Cold and Flu Drug Facts

Active ingredients (in each 15 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer Cough suppressant Nasal decongestant

Uses

- temporarily relieves common cold/flu symptoms:
- nasal congestion
- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever

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
- high blood pressure
- thyroid disease
- diabetes
- 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, 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 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 7 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

butylated hydroxyanisole, edetate disodium, FD&C yellow no. 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

Multi-Symptom Relief

Compare to Vicks® DayQuil® Cold & Flu active ingredients

Non-Drowsy

Daytime Cold & Flu

Acetaminophen, Phenylephrine HCl, Dextromethorphan HBr

Pain Reliever, Fever Reducer, Cough Suppressant, Nasal Decongestant

ALCOHOL FREE

Original Flavor

8 FL OZ (237 mL)



Drug Facts (continued)

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
- 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 phiegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, 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
- new symptoms occur
- you get nervous, dizzy or sleepless redness or swelling is present
- fever gets worse or lasts more than 3 days
- pain, nasal congestion or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

Drug Facts (continued)

children under 4 vrs

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 vrs 15 mL every 4 hrs children 4 to under 6 yrs ask a doctor

do not use

Other Information ■ each 15 mL contains: sodium 7 mg ■ store at 20-25°C (68-77°F)

Inactive Ingredients butylated hydroxyanisole, edetate disodium, FD&C yellow no. 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

BASIC CARE DAYTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl solution

Product Information

HUMAN OTC DRUG NDC:72288-656 **Item Code (Source) Product Type**

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	
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	MENTHOL (with fruit)	Imprint Code	
Contains			

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72288-656- 40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/20/2021	
2	NDC:72288-656- 34	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/20/2021	

Labeler - Amazon.com Services LLC (128990418)

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