

DAY TIME COLD AND FLU COLD AND FLU MULTI SYMPTOM RELIEF- acetaminophen, dextromethorphan hbr, phenylephrine hcl solution
We Care Distributor Inc.

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.

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/child takes

- more than 4 doses in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

Sore throat warning: If sore throat is severe, lasts for more than 2 days, occurs with or followed by fever, headache, rash, nausea, or vomiting, see 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.

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- diabetes
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- 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 the blood thinning drug warfarin

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- new symptoms occur
- redness or swelling is present
- symptom gets worse or lasts more than 5 days (children) or 7 days (adults)
- fever gets worse or lasts more than 3 days
- 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: Taking more than directed cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. 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
- use dose cup
- do not exceed 4 doses per 24 hrs
- adults & children 12 years and over: 30 mL every 4 hrs
- children 6 to under 12 years: 15 mL every 4 hrs
- children under 12 years: ask a doctor

When using Day Time and Night Time products; carefully read each label to ensure correct dosing

Other information

- protect from freezing
- each tablespoon contains: sodium 46 mg
- store at room temperature 15-30°C (59-86°F)

Inactive ingredients

citric acid, FD&C yellow no. 6, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose

Questions or comments?

1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com

Principal Display Panel

SEE NEW WARNINGS

Compare to DayQuil® Cold & Flu Active Ingredients

Non-Drowsy

DayTime Cold & Flu

Pain Reliever, Fever Reducer, Cough Suppressant, Nasal Decongestant Multi-Symptom Relief

Aches, fever - Acetaminophen

Cough - Dextromethorphan HBr

Nasal congestion - Phenylephrine HCl

Alcohol Free and Antihistamine Free

4 FL OZ (120 mL)

NDC: 70005-045-01

We Care
FOR GOOD HEALTH

DAY TIME COLD & FLU

COMPARE TO ACTIVE INGREDIENTS IN Vicks® DayQuil®**

Pain Reliever, Fever Reducer
Cough Suppressant, Nasal Decongestant

Multi-Symptom Relief

This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® DayQuil®

4 FL OZ (120 mL) Liquid

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF PRINTED INNER CAP SEAL IS BROKEN OR MISSING

Drug Facts

Active ingredients (in each 15 mL) Purpose
Acetaminophen 325 mg Pain reliever/fever reducer
Dextromethorphan HBr 10 mg Cough suppressant
Phenylephrine HCl 5 mg Nasal decongestant

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

Warnings
Liver warning: This product contains acetaminophen. Severe liver damage may occur if adult/child takes more than 4 doses in 24 hours, which is the maximum daily amount of this product with other drugs containing acetaminophen.
adult has 3 or more alcoholic drinks everyday while using this product.
Sore throat warning: If sore throat is severe, lasts for more than 2 days occurs with or is followed by fever, headache, rash, nausea, or vomiting, see a doctor promptly.

Do not use: with any other drug containing acetaminophen (prescription or non-prescription). 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.

Ask a doctor before use if you have liver disease heart disease high blood pressure diabetes thyroid disease trouble urinating due to an enlarged prostate gland cough that occurs with too much phlegm (mucus) a cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema a sodium restricted diet

Manufactured For / Distributed by:
We Care Distributor Inc.
Hermilane, TN 37076
www.wecaredistributor.com

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LOV/Exp

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Drug Facts (continued)

Ask a doctor before use if you have ■ liver disease ■ heart disease ■ high blood pressure ■ diabetes ■ thyroid disease ■ trouble urinating due to an enlarged prostate gland ■ cough that occurs with too much phlegm (mucus) ■ a cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema ■ a sodium restricted diet

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

Stop use and ask doctor if ■ you get nervous, dizzy, or sleepless ■ new symptoms occur ■ redness or swelling is present ■ symptoms get worse or lasts more than 5 days (children) or 7 days (adults) ■ fever get worse lasts more than 3 days ■ 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: Taking more than directed can cause serious health problem. In case of overdose get medical help or contact a Poison control center right away. Quick medical attention is critical for adults and children even if you do not notice any signs or symptoms

Directions ■ take only as directed ■ see overdose warning ■ use dose cup ■ do not exceed 4 doses in 24 hours

adults and children 12 years and over	30 mL every 4 hours
children 6 to under 12 years	15 mL every 4 hours
children under 12 years	ask a doctor

■ when using day time or night time products, carefully read each label to ensure correct dosing

Other information ■ protect from freezing ■ each tablespoon contains: sodium 46 mg ■ store at room temperature 15°-30° C (59°-86° F)

Inactive ingredients citric acid, FD&C yellow no. 6, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose

DAY TIME COLD AND FLU COLD AND FLU MULTI SYMPTOM RELIEF

acetaminophen, dextromethorphan hbr, phenylephrine hcl solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70005-045
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	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
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Product Characteristics

Color	ORANGE (clear)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70005-045-01	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/30/2016	

Labeler - We Care Distributor Inc. (079832998)

Establishment

Name	Address	ID/FEI	Business Operations
PURINE PHARMA LLC		019950491	manufacture(70005-045)

Revised: 8/2016

We Care Distributor Inc.