

DAYTIME COLD AND FLU RELIEF NON DROWSY- acetaminophen, dextromethorphan hbr, phenylephrine hcl liquid
Walgreen Company

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.

Walgreen Co. Cold & Flu Relief Drug Facts

Active ingredients (in each 15 ml tablespoon)

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. The maximum daily dose of this product is 4 doses (adult: 2,600 mg acetaminophen; child: 1,300 mg acetaminophen) in 24 hours. 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, which is the maximum daily amount
- taken 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 is 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
- thyroid disease
- diabetes
- high blood pressure
- 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

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.

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 Liver warning
 - use dose cup
 - do not exceed 4 doses per 24 hrs
-

adults & children 12 yrs & over	30 ml (2 TBSP) every 4 hrs
children 6 to under 12 yrs	15 ml (1 TBSP) every 4 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

- when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

Other information

- each tablespoon 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

NON-DROWSY - DAYTIME

Cold & Flu Relief

Acetaminophen / Aches / Fever

Dextromethorphan HBr / Cough

Phenylephrine HCl / Nasal Congestion

Pain reliever, fever reducer, cough suppressant & nasal decongestant

Alcohol free

Antihistamine free

Compare to Vicks® DayQuil® active ingredients

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

WALGREENS PHARMACIST RECOMMENDED*

NON-DROWSY • DAYTIME

Cold & Flu Relief

Acetaminophen / Aches / Fever
Dextromethorphan HBr / Cough
Phenylephrine HCl / Nasal Congestion

- Pain reliever, fever reducer, cough suppressant & nasal decongestant
- Alcohol free
- Antihistamine free

Gluten Free ORG0612

Compare to Vicks® DayQuil® active ingredients†

8 FL OZ (237 mL)

PEEL BACK AT CORNER FOR MORE INFORMATION →

Drug Facts

Active ingredients (in each 15 ml tablespoon) 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:

- headache ■ sore throat ■ minor aches and pains
- fever ■ nasal congestion
- cough due to minor throat and bronchial irritation

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200 WILMOT RD.
DEERFIELD, IL 60015
100% SATISFACTION
GUARANTEED
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Drug Facts (continued)

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Drug Facts (continued)

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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

DAYTIME COLD AND FLU RELIEF NON DROWSY			
acetaminophen, dextromethorphan hbr, phenylephrine hcl liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0656
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
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JH2SW)	
POLYETHYLENE GLYCOL (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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0656-30	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/28/2006	
2	NDC:0363-0656-38	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/07/2006	
3	NDC:0363-0656-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/15/2007	
4	NDC:0363-0656-34	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/04/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/07/2006	

Labeler - Walgreen Company (008965063)