

DAY TIME COLD NON DROWSY COLD AND FLU RELIEF- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled
Chain Drug Consortium, 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.

Drug Facts

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 15 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

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

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

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.

Ask a doctor before use if you have

- liver disease
- diabetes
- heart disease
- thyroid disease
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

When using this product,

do not exceed the recommended dosage.

Stop use and ask a doctor if

- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- new symptoms occur
- nervousness, dizziness or sleeplessness occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- 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 the recommended dose can cause liver damage. 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

- **do not take more than directed (see Overdose warning)**
- do not take more than 4 doses in 24 hours
- adults and children 12 years and over: take 2 softgels with water every 4 hours
- swallow whole; do not crush, chew, or dissolve
- children under 12 years: do not use
- **when using other Day time or Night time products, carefully read each label to insure correct dosing**

Other information

- store at room temperature 15°-30°C (59°-86°F)
- avoid excessive heat

Inactive ingredients

butylated hydroxyanisole, butylated hydroxytoluene, carmine, D&C yellow #10, FD&C red #40, FD&C

yellow #6, gelatin, glycerin USP, mannitol, polyethylene glycol 400 NF, polyethylene glycol 600, povidone, propylene glycol USP, sodium metabisulfite, sorbitan, sorbitol

Principal Display Panel

Premier Value

Day- Time

Non- Drowsy Cold/ Flu Relief

Acetaminophen, Dextromethorphan HBr, Phenylephrine HCl

Pain reliever, fever reducer, cough suppressant, nasal decongestant

*Compare to active ingredients in Vicks® DayQuil®

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

SEE NEW WARNINGS INFORMATION

DISTRIBUTED BY:

CHAIN DRUG CONSORTIUM, LLC.

2300 NW CORPORATE BLVD., SUITE 115

BOCA RATON, FL 33431

QUESTIONS OR COMMENTS ?

CALL TOLL FREE 1-877-753-3935

Product Label

Drug Facts

Active Ingredients (in each softgel) Purpose
 Acetaminophen 325 mg, USP Pain reliever/fever reducer
 Dextromethorphan Hydrobromide 10 mg Cough suppressant
 Phenylephrine HCl 5 mg Nasal decongestant

Uses
 Temporarily relieves common cold/flu symptoms:
 ■ muscle aches ■ headache ■ nasal congestion ■ cough
 ■ minor aches ■ pains ■ sore throat pain ■ fever

Warnings Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:
 ■ more than 6 doses in 24 hours, which is the maximum daily amount
 ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product

Sore throat warning: If sore throat is severe, persists more than 2 days, is accompanied by fever, nausea, rash, or vomiting, consult a doctor promptly.

Overdose warning: Taking more than the recommended dose (overdose) could cause serious health problems.
 In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Do not use
 ■ with other drugs containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ if you are taking a prescription, 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 ■ thyroid disease ■ diabetes ■ high blood pressure ■ persistent or chronic asthma ■ emphysema ■ persistent or chronic

Inactive ingredients
 "butylated hydroxytoluene," "butylated hydroxyanisole," "butylated hydroxytoluene," "carmine," "gelatin," "glycerin USP," "maltitol," "polyethylene glycol 400 NF," "polyethylene glycol 600," "povidone," "propylene glycol USP," "purified water USP," "sodium metabisulfite," "sorbitan," "sorbitol," "sorbitol special," and white edible ink. *May also contain

Other information
 ■ store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat ■ This product does not contain phenylpropanolamine (PPA) ■ This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® DayQuil®

Directions
 ■ take every 4 hours ■ do not exceed more than 6 doses in 24 hours or as directed by a doctor. If taking DAY-TIME and NIGHT-TIME softgels limit total to 4 doses per day. adults and children swallow 2 softgels with water 12 years of age and older ask a doctor children 4 to 12 years of age ask a doctor children under 4 years of age do not use

If pregnant or breast-feeding, ask a health care professional before use. **Keep out of reach of children.**
 These could be signs of a serious condition.
 ■ symptoms occur ■ symptoms do not get better within 7 days ■ sleepless ■ fever gets worse or lasts more than 3 days ■ new symptoms occur ■ you get nervous, dizzy, or (for adults) or 5 days (for children)

Stop use and ask a doctor if
 ■ you get nervous, dizzy, or (for adults) or 5 days (for children)

When using this product, do not exceed the recommended dosage
 ■ do not use with other products containing acetaminophen ■ do not take for more than 7 days

Ask a doctor or pharmacist before use if you are
 ■ taking the blood thinning drug warfarin ■ breathing problems ■ cough associated with smoking ■ trouble urinating due to an enlarged prostate gland ■ sleepless ■ fever gets worse or lasts more than 3 days ■ new symptoms occur ■ you get nervous, dizzy, or (for adults) or 5 days (for children)

THIS PRODUCT IS SEALED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE.
 USE ONLY IF BLISTERS ARE INTACT.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Lot No.:
 Exp. Date:

Premier Value DAY-TIME Non-Drowsy Cold/Flu Relief

SEE NEW WARNINGS INFORMATION

NDC 68016-470-20

*Compare to Active Ingredients in Vicks® DayQuil®

Premier Value DAY-TIME Non-Drowsy Cold/Flu Relief

Acetaminophen
Dextromethorphan Hydrobromide, Phenylephrine HCl
Pain Reliever • Fever Reducer
Cough Suppressant • Nasal Decongestant
20 Softgels

PREMIER VALUE GUARANTEE

DISTRIBUTED BY:
 CHAIN DRUG CONSORTIUM, LLC.
 2300 NW CORPORATE BLVD., SUITE 115
 BOCA RATON, FL 33431
 Questions or comments?
 Call toll free 1-877-753-3935

PLD-F
 F47DCPV20

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

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KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Drug Facts (continued)
 polyethylene glycol 400 NF, polyethylene glycol 600, povidone, propylene glycol USP, purified water USP, sodium metabisulfite, sorbitan, sorbitol, sorbitol special, and white edible ink. *May also contain

DAY TIME NON DROWSY COLD/ FLU RELIEF

DAY TIME COLD NON DROWSY COLD AND FLU RELIEF			
acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-470
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
POVIDONES (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	ORANGE (RED)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	P19;95A;36A
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-470-20	2 in 1 CARTON		
1		10 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	07/12/2010	

Labeler - Chain Drug Consortium, LLC (101668460)

Revised: 10/2015

Chain Drug Consortium, LLC