# COLD AND FLU RELIEF- acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled Chain Drug Consortium, LLC

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## **Drug Facts**

# Active ingredients (in each softgel)

## Acetaminophen 325 mg

Dextromethoprhan HBr 10 mg

Phenlyephrine HCl 5 mg

#### **Purposes**

#### Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

#### Uses

- temporarily relieves these 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 everyday while using this product

Allery 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

- 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.
- 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.

#### Ask a doctor before use if the user has

- 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 recommended dosage.

# Stop use and ask a doctor if

- pain, cough or nasal congestion gets worse or lasts more than 7 days
- nervousness, dizziness, or sleeplessness occur
- 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:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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-hour
- 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 Daytime and Nighttime products, carefully read each label to ensure correct dosing

#### Other information

- store between 15-30°C (59-86°)
- avoid excessive heat

### **Inactive ingredients**

FD&C yellow #6, FD&C red #40, gelatin, glycerin, lecithin, light mineral oil, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol white ink

#### **Questions or comments?**

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

# **Principal Display Panel**

\*COMPARE TO HE ACTIVE INGREDIENTS IN VICKS® DAYQUIL® COLD & FLU LIQUICAPS®

Daytime, Multi-Symptom

**Cold & Flu Relief** 

Acetaminophen 325 mg

Pain reliever/Fever reducer

**DEXTROMETHORPHAN HBr** 10 mg

Cough suppressant

PHENYLEPHRINE HCI 5 mg

**Nasal Decongestant** 

Relieves: Aches •Fever •Sore Throat Cough • Nasal Congestion

Non-drowsy, Alcohol-free, Antihistamine-free

Softgels\*\*

(\*\*Liquid-filled Capsules)

# TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOW ANY SIGNS OR TAMPERING.

# KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

\*This product is not manufactured or distributed by The Procter & Gamble Company. Vicks® DayQuil® and LiquiCaps® are registered trademarks of The Procter & Gamble Company.

Distributed by: Pharmacy Value Alliance, LLC 407 East Lancaster Avenue, Wayne, PA 19087

**Package Label** 

When using this product, do not exceed recommended dosage.

thinning drug warfarin.

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

- condy that occurs with too much phiegm (mucus) ешреучены
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- do not know if your prescription drug contains an MAOI, ask a doctor or Parkinson's disease), or for 2 weeks after stopping the MAOI drug, if you (certain drugs for depression, psychiatric, or emotional conditions, or
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  - nonprescription). If you are not sure whether a drug contains with any other drug containing acetaminophen (prescription or

vomiting, consult a doctor promptly.

days, is accompanied or followed by fever, headache, rash, nausea, or Sore throat warning: If sore throat is severe, persists for more than 2 It a skin reaction occurs, stop use and seek medical help right away. may include: skin reddening blisters rash

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms

- 3 or more alcoholic drinks every day while using this product
  - with other drugs containing acetaminophen
  - more than 4,000 mg of acetaminophen in 24 hours may occur if you take:

Liver warning: This product contains acetaminophen. Severe liver damage Warnings

**Drug Facts** (continued)

C9II 1-811-123-3332 Woudey-Friday 9AM-5PM EST Unestions or comments??

glycol, purified water, sorbitan, sorbitol, white ink lecithin, light mineral oil, mannitol, polyethylene glycol, povidone, propylene Inactive ingredients FD&C red #40, FD&C yellow #6, gelatin, glycerin,

> ■ store between 15-30°C (59-86°F)
> ■ avoid excessive heat Other information

#### label to ensure correct dosing

- when using other Daytime or Mighttime products, carefully read each
  - children under 12 years: do not use
- swallow whole; do not crush, chew, or dissolve ■ squits and children 12 years and over: take 2 softgels with water every 4 hours
  - do not take more than 4 doses in 24 hours

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    - fever gets worse or lasts more than 3 days
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    - Stop use and ask a doctor if

Drug Facts (continued)

Nasal decongestant Phenylephrine HCl 5 mg. Congh suppressant Dextromethorphan HBr 10 mg. SIN TELEVET/TEVET TECLUCET Purposes (lagitos dasa ni) sinaibargni avidak)

Drug Facts

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gund Lacts (continued)

\*COMPARE TO THE **ACTIVE INGREDIENTS IN** VICKS® DAYQUIL® COLD & FLU LIQUICAPS®



Daytime, Multi-Symptom

# Cold & Flu Relief

# ACETAMINOPHEN 325 mg

Pain reliever/Fever reducer

# **DEXTROMETHORPHAN HBr 10 mg**

Cough suppressant

# PHENYLEPHRINE HCI 5 mg

Nasal Decongestant

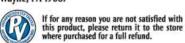
Relieves: Aches • Fever • Sore Throat

Cough • Nasal Congestion

Non-drowsy, Alcohol-free, Antihistamine-free

COMPLETE WARNINGS AND PRODUCT INFORMATION IS OPENED OR IF BLISTER SIGNS OF TAMPERING. TAMPER EVIDENT: DO NOT USE IF CARTON I UNIT IS TORN, BROKEN OR SHOWS ANY KEEP OUTER CARTON FOR \*This product is not manufactured or distributed by The Procter & Gamble Company. Vicks®, DayQuil®, and LiquiCaps® are registered trademarks of The Procter & Gamble Company.

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#### PREMIER VALUE Cold and Flu Relief

#### **COLD AND FLU RELIEF**

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68016-797

Route of Administration ORAL

#### **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) **ACETAMINOPHEN** 325 mg **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) **DEXTROMETHORPHAN** 10 mg **HYDROBROMIDE** (DEXTROMETHORPHAN - UNII:7355X3ROTS) PHENYLEPHRINE HYDROCHLORIDE (UNII: 04|A59TNS|) (PHENYLEPHRINE -**PHENYLEPHRINE** 5 mg UNII:1WS297W6MV) **HYDROCHLORIDE**

Inactive Ingredients	
Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SORBITOL (UNII: 506T60A25R)	
POVIDONE (UNII: FZ989GH94E)	
SORBITAN (UNII: 6092ICV9RU)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics			
Color	orange	Score	no score
Shape	OVAL	Size	20mm

Flavor	Imprint Code	PC9
Contains		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:68016-797- 16	16 in 1 CARTON	09/02/2022	09/30/2026		
1		1 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 Drug	M012	09/02/2022	09/30/2026

Labeler - Chain Drug Consortium, LLC (101668460)

Revised: 6/2025 Chain Drug Consortium, LLC