

COLD AND FLU RELIEF DAYTIME NON DROWSY- acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled
Harris Teeter, 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 5 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 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 Daytime or Nighttime 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, edible white ink, FD&C red #40*, FD&C yellow

#6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol

*may contain this ingredient

Questions or comments?

1-800-432-6111

Principal Display Panel

†Compare to the active ingredients in Vicks® DayQuil® LiquiCaps®

Daytime Non-Drowsy

Cold & Flu Relief

Multi-Symptom Relief

Acetaminophen

Dextromethorphan HBr, Phenylephrine HCl

- Aches, Fever, Sore Throat
- Cough
- Nasal Congestion

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 SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

PROUDLY DISTRIBUTED BY:

HARRIS TEETER, LLC

MATTHEWS, NC 28105

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

Package Label



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1-800-432-6111

Questions or comments?

Inactive ingredients butylated hydroxyanisole, butylated hydroxytoluene, edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, polydioxane, propylene glycol, purified water, sorbitan, sorbitol* may contain this ingredient

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

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 Daytime or Nighttime products, carefully read each label to insure correct dosing

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. **Keep out of reach of children.** If pregnant or breast-feeding, ask a health professional before use. These could be signs of a serious condition. ■ cough comes back or occurs with rash or headache that lasts ■ redness or swelling is present ■ fever gets worse or lasts more than 3 days

Drug Facts (continued)

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

When using this product, do not exceed recommended dosage.

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

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

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.

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Drug Facts (continued)



Daytime Non-Drowsy Cold & Flu Relief

MULTI-SYMPATOM RELIEF

**ACETAMINOPHEN,
DEXTROMETHORPHAN HBr, PHENYLEPHRINE HCl**

- ACHES, FEVER, SORE THROAT • COUGH
- NASAL CONGESTION

Alcohol-Free
Antihistamine-Free

24 Softgels**



NON-DROWSY

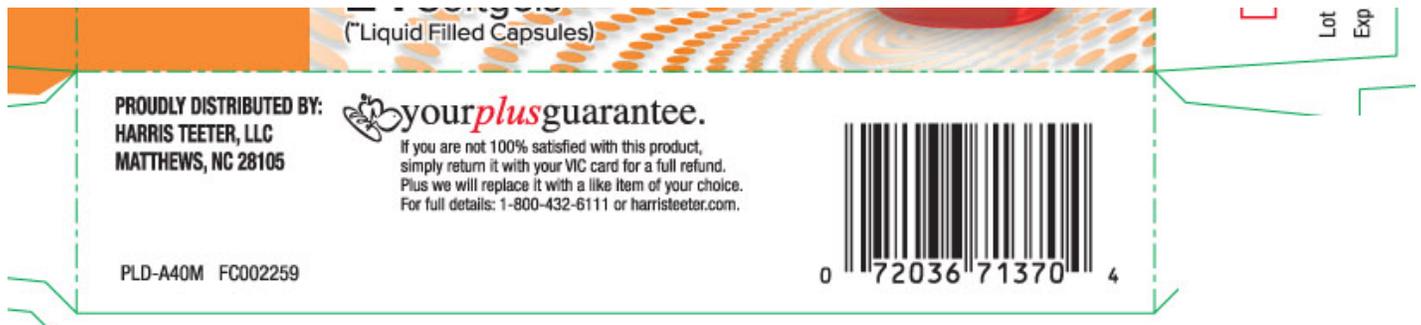
Daytime Non-Drowsy

*Compare to the active ingredients in Vicks® DayQuil® LiquiCaps®

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No.:
Date:



Harris Teeter Cold and Flu Relief Softgels

COLD AND FLU RELIEF DAYTIME NON DROWSY

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69256-470
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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	P19;95A
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69256-470-24	24 in 1 CARTON		
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 FINAL	part341	02/28/2015	

Labeler - Harris Teeter, LLC (048463103)

Revised: 3/2015

Harris Teeter, LLC