# HARRIS TEETER NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate 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.

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# Harris Teeter, LLC Night Time Cold & Flu Drug Facts

# Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

# Purpose

Pain reliever/fever reducer Cough suppressant Antihistamine

#### Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

### **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

**Allergy 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, lasts 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.
- 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
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough as occurs with smoking, asthma, or emphysema
- trouble urinating due to an enlarged prostate gland

## Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

#### When using this product

- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

### Stop use and ask a doctor if

- pain or cough gets worse or lasts more than 7 days
- 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:**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 overdose warning
- do not exceed 4 doses per 24 hours

adults & children 12 yrs & over	2 softgels with water every 6 hrs	
children 4 to under 12 yrs	ask a doctor	
children under 4 yrs	do not use	

#### Other information

• store at 20-25°C (68-77°F)

# **Inactive ingredients**

D&C yellow no. 10, edible ink\*, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution \*may contain this ingredient

#### Questions or comments?

1-800-719-9260

## Package/Label Principal Display Panel

NightTime

Compare to the active ingredients in Vicks® NyQuil® Cold & Flu LiquiCaps®

Pain Reliever/Fever Reducer • Acetaminophen

Cough Suppressant ● Dextromethorphan HBr

Antihistamine • Doxylamine Succinate

COLD & FLU

Multi-Symptom Relief

Aches, Fever & Sore Throat

Sneezing, Runny Nose

Cough

24 SOFTGELS

Actual Size







# **NightTime**

Compare to the active ingredients in Vicks® NyQuil® Cold & Flu LiquiCaps®\*\*

Pain Reliever/Fever Reducer · Acetaminophen Cough Suppressent · Dextromethorphan HBr Antihistamine · Doxylamine Succinate

# COLD & FLU

# Multi-Symptom Relief

- Aches, Fever & Sore Throat
- Sneezing, Runny Nose
- Cough

24 SOFTGELS





Cold & Flu LiquiCaps®. \*\* This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® MyQuill®

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povidone, p.mp. yen e gycol

Made in Canada Proudly distributed BY: Harrist Eeter, LLC, Matthews, NC2 8105 dible ink\*, FD&C blue no. 1, galath, glycein, polyethylene \*ma ycon tain this ingred is nt

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# HARRIS TEETER NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69256-056	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg	
<b>DO XYLAMINE SUCCINATE</b> (UNII: V9 BI9 B5YI2) (DO XYLAMINE - UNII:95Q B77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg	

Inactive Ingredients		
Ingredient Name	Strength	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)		
PO VIDO NE (UNII: FZ989 GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SORBITOL (UNII: 506T60A25R)		
SORBITAN (UNII: 6 O92ICV9RU)		

# **Product Characteristics**

Color	GREEN (clear)	Score	no score
Shape	OVAL	Size	20 mm
Flavor		Imprint Code	056
Contains			

	Packaging			
	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
ı	1 NDC:69256-056-62	12 in 1 CARTON	11/21/2015	
	1	2 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	11/21/2015	

# Labeler - Harris Teeter, LLC (048463103)

Revised: 12/2019 Harris Teeter, LLC