

**HARRIS TEETER DAYTIME- acetaminophen, dextromethorphan hbr, phenylephrine hcl solution**

**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 DayTime Drug Facts**

**Active ingredients (in each 15 mL)**

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. 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
- taken with other drugs containing acetaminophen
- adult has 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, 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.
- 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 such 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.**

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
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 4 hrs
children 6 to under 12 yrs	15 mL every 4 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

### Other information

- each 15 mL 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

Compare to the active ingredients in Vicks® DayQuil® Cold & Flu

DayTime

Pain Reliever/Fever Reducer – Acetaminophen

Cough Suppressant – Dextromethorphan HBr

Nasal Decongestant – Phenylephrine HCl

COLD & FLU

Multi-Symptom Relief

Aches, Fever, Sore Throat

Nasal Congestion

Cough

Non-Drowsy

Alcohol Free/Antihistamine Free

12 FL OZ (355 mL)

See New Warnings

**Drug Facts** (continued)

■ 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 ■ cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

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**Questions or comments?** 1-800-719-0260

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

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



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



# DayTime

**Pain Reliever/Fever Reducer • Acetaminophen  
Cough Suppressant • Dextromethorphan HBr  
Nasal Decongestant • Phenylephrine HCl**

**COLD & FLU**

Multi-Symptom Relief

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

**Non-Drowsy**  
Alcohol Free/Antihistamine Free

**12 FL OZ (355 mL)**

See New Warnings

**Drug Facts** **DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING**

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

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**Stop use and ask a doctor if** ■ you get nervous, dizzy or sleepless ■ new symptoms occur

**CODE AREA**  
\* no varnish \* no color  
65640 HT F2

## HARRIS TEETER DAYTIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69256-656
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)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	

SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MENTHOL (UNII: L7T10EP3A)	

### 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:69256-656-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/24/2015	
2	NDC:69256-656-34	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/20/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/24/2015	

### Labeler - Harris Teeter, LLC (048463103)