

**HARRIS TEETER DAYTIME NIGHTTIME- acetaminophen, dextromethorphan hbr,
doxylamine succinate, phenylephrine hcl
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.

Harris Teeter, LLC DayTime NightTime Drug Facts

Active ingredients (in each softgel) – Nighttime Cold & Flu

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

Active ingredients (in each softgel) – Daytime Cold & Flu

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purpose – Nighttime Cold & Flu

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Purpose – Daytime Cold & Flu

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses – Nighttime Cold & Flu

- 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

Uses – Daytime Cold & Flu

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 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 – Nighttime Cold & Flu

- 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 before use if you have – Daytime Cold & Flu

- liver disease
- heart disease

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

Ask a doctor or pharmacist before use if you are – Nighttime Cold & Flu

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

Ask a doctor or pharmacist before use if you are – Daytime Cold & Flu

taking the blood thinning drug warfarin

When using this product – Nighttime Cold & Flu

- 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

When using the product – Daytime Cold & Flu

do not use more than directed

Stop use and ask a doctor if – Nighttime Cold & Flu

- 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.

Stop use and ask a doctor if – Daytime Cold & Flu

- you get nervous, dizzy or sleepless
- pain, nasal congestion 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 – Nighttime Cold & Flu

- take only as directed – see overdose warning
- do not exceed 4 doses per 24 hrs

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

Directions – Daytime Cold & Flu

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children 4 to under 12 yrs	ask a doctor
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Other information

- store at 20-25°C (68-77°F)

Inactive ingredients – Nighttime Cold & Flu

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

Inactive ingredients – Daytime Cold & Flu

edible ink*, FD&C red no. 40, FD&C yellow no. 6, 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

Convenience Pack

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

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

32 SOFTGELS

Actual Size

NightTime

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

16 SOFTGELS

Actual Size



<p>DayTime Cold & Flu</p> <p>Drug Facts</p> <p>Active ingredients (in each softgel)</p> <p>Pain reliever/fever reducer Acetaminophen 325 mg</p> <p>Cough suppressant Dextromethorphan HBr 10 mg</p> <p>Nasal decongestant Phenylephrine HCl 5 mg</p> <p>Purpose</p> <p>Uses: temporarily relieves common cold/flu symptoms cough due to minor throat and bronchial irritation</p> <p>Warnings</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours</p> <p>with other drugs containing acetaminophen</p> <p>3 or more alcoholic drinks every day while using this product</p> <p>Alert: acetaminophen may cause severe skin reactions.</p> <p>Symptoms may include: ■ skin reddening ■ blisters ■ rash</p> <p>If a skin reaction occurs, stop use and seek medical help right away.</p>	<p>NightTime Cold & Flu</p> <p>Drug Facts</p> <p>Active ingredients (in each softgel)</p> <p>Pain reliever/fever reducer Acetaminophen 325 mg</p> <p>Cough suppressant Dextromethorphan HBr 15 mg</p> <p>Antihistamine Doxylamine succinate 6.25 mg</p> <p>Purpose</p> <p>Uses: temporarily relieves common cold/flu symptoms cough due to minor throat and bronchial irritation</p> <p>■ minor aches and pains ■ sore throat ■ headache</p> <p>■ runny nose and sneezing ■ fever</p> <p>Warnings</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours</p> <p>with other drugs containing acetaminophen</p> <p>3 or more alcoholic drinks every day while using this product</p> <p>Alert: acetaminophen may cause severe skin reactions.</p> <p>Symptoms may include: ■ skin reddening ■ blisters ■ rash</p> <p>If a skin reaction occurs, stop use and seek medical help right away.</p>
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Convenience Pack

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

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



32 SOFTGELS

NightTime

- Pain Reliever/Fever Reducer**
- Acetaminophen
- Cough Suppressant**
- Dextromethorphan HBr
- Antihistamine**
- Doxylamine Succinate

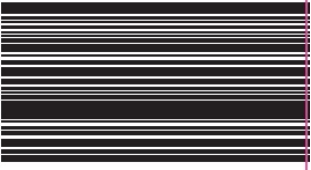
COLD & FLU

Multi-Symptom Relief

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



16 SOFTGELS



58072 HT 02

0 72036 71466 4



OPEN OTHER END

Drug Facts (continued)

See this at 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.
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- 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
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 - trouble urinating due to an enlarged prostate gland

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

When using this product

- excitability may occur, especially in children
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- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
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Stop use and ask a doctor if

- pain or cough gets worse or lasts more than 7 days
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- redness or swelling is present
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Drug Facts (continued)

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When using this product do not use more than directed**Stop use and ask a doctor if**

- you get nervous, dizzy or sleepless
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- fever gets worse or lasts more than 3 days
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Drug Facts (continued)

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 hrs
- | | |
|---------------------------------|-----------------------------------|
| 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, polydioxane, polyethylene glycol, purified water, sorbitol sorbitan solution *may contain this ingredient

Questions or comments? 1-800-719-9260

Drug Facts (continued)

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Questions or comments? 1-800-719-9260

DO NOT USE IF BLISTER UNIT IS BROKEN OR DAMAGED
 *These products are not manufactured or distributed by Procter & Gamble, distributor of Vicks® DayQuil® Cold & Flu Liquid Caps® and Vicks® NyQuil® Cold & Flu Liquid Caps®.

MADE IN CANADA
 PROUDLY DISTRIBUTED BY:
 HARRIS TEETER, LLC
 MATTHEWS, NC 28105

yourplusguarantee.
 1-800-432-6111 or harrisdealer.com

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

CONVENIENT RECYCLING TAB

HARRIS TEETER DAYTIME NIGHTTIME

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69256-580
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69256-580-72	1 in 1 CARTON; Type 0: Not a Combination Product	11/21/2015	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	8 BLISTER PACK	16
Part 2	16 BLISTER PACK	32

Part 1 of 2**HARRIS TEETER NIGHTTIME**

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information

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	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	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: PDC6A3C0OX)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	

Part 2 of 2

HARRIS TEETER DAYTIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information

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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	L994
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	

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: 11/2018

Harris Teeter, LLC