## DAYTIME COLD AND FLU- acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled Kroger Company

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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#### Kroger Co. DayTime Cold & Flu 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/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

- 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

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 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 hrs

adults & children 12 yrs & over	2 softgels with water every 4 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**

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?

1-800-632-6900

#### **Principal Display Panel**

COMPARE TO the active ingredients of VICKS® DAYQUIL® COLD & FLU

See side panel

POWERFUL NON-DROWSY RELIEF

**OUR PHARMACIST RECOMMEND** 

Cold & Flu

DayTime

Multi-Symptom Relief

Acetaminophen

Dextromethorphan HBr

Phenylephrine HCl

Pain Reliever

Fever Reducer

Cough Suppressant

Nasal Decongestant

**48 SOFTGELS** 

actual size





#### Drug Facts

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

Active ingredients (in each softgel)

Purpose

ain reliever/fever reducer

Dextromethorphan HBr 10 mg. Phenylephrine HCl 5 mg......

...Cough suppressant

.. Nasal de congestant

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

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- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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- If you are not sure whether a drug contains a cetaminophen, 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

- diabetes high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland cough that occurs with too much philegm (mucus)
- persistent or chronic cough 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 ■ new symptoms occur

- you get nervous, dizzy or sleepless
- fever gets worse or lasts more than 3 days
- redness or swelling is present

- pain, nasal congestion or cough gets worse or lasts more than 7 days
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

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# Drug Facts (continued)

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hwater every4 hs

Other Information sbreat 20:25°C 68-77°F)

am ble Company, Cincinnati, Ol

5202. The Procter & Gamble

www.StopMedicineAbuse.org

Inactive ingredients edibe ink., 10.80 red no. 40, 10.80 yelow no. 6, gelatin, glycorin, polyethyleneglycol, povidone, popyleneglycol, purified water, sorbitol sorbitan solution "may containthis ingredent

Questions ar comments? 1 800 632-800

QUALITY GUARANTEE

**GLUTEN FREI** 

STRIBUTED BY THE KROGER CO. NCINNATI, OHIO 4 5202

AADE INCANADA

#### OPEN OTHER END







#### **DAYTIME COLD AND FLU**

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-704
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	10 mg	
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (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, UNSPECIFIED (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6 A3C0 OX)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
PO VIDONE, UNSPECIFIED (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	20 mm	
Flavor		Imprint Code	L994	
Contains				

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:30142-704-62	12 in 1 CARTON	09/30/2014		
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2	NDC:30142-704-67	24 in 1 CARTON	09/30/2014		
2		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	09/30/2014		

### Labeler - Kroger Company (006999528)

Revised: 4/2020 Kroger Company