NIGHT TIME COLD AND FLU- acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride solution
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.

Kroger Co. Night Time Cold & Flu Drug Facts

Active ingredients (in each 20 mL)

Acetaminophen 650 mg

Diphenhydramine HCl 25 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Antihistamine/cough suppressant

Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
- cough
- nasal congestion
- minor aches and pains
- sinus congestion and pressure
- sore throat
- headache
- runny nose
- sneezing
- temporarily reduces fever
- controls cough to help you get to sleep

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, 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.
- with any other product containing diphenhydramine, even one used on skin
- 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
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- 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
- taking sedatives or tranquilizers

When using this product

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- 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

- **do not take more than directed (see Overdose warning)**
- do not take more than 5 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- adults and children 12 years of age and older: 20 mL in dosing cup provided every 4 hours
- children under 12 years of age: do not use

Other information

- **each 20 mL contains:** sodium 7 mg
- store at 20-25°C (68-77°F)
- dosing cup provided
- do not refrigerate

Inactive ingredients

anhydrous citric acid, benzyl alcohol, edetate disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, triethyl citrate, xanthan gum

Questions or comments?

1-800-632-6900

Package/Label Principal Display Panel

COMPARE TO the active ingredients of MUCINEX® FAST-MAX® NIGHT TIME COLD & FLU

See back panel

for ages 12+
OUR PHARMACIST RECOMMENDED
Maximum Strength
FAST NIGHTTIME
Cold & Flu
Acetaminophen
Pain Reliever/Fever Reducer
Diphenhydramine HCl
Antihistamine/Cough Suppressant
Phenylephrine HCl
Nasal Decongestant
1 FOR ALL RELIEF
NASAL CONGESTION
SNEEZING, RUNNY NOSE
ACHES, HEADACHE
COUGH, ITCHY THROAT
6 FL OZ (180 mL)

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING.

DIST. BY THE KROGER CO.
CINCINNATI, OHIO 45202
QUALITY GUARANTEE
800-632-6900
www.kroger.com
GLUTEN FREE

0 41260 00336 3

Drug Facts

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Diphenhydramine HCl 25 mg	Antihistamine/cough suppressant
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■ controls cough to help you get to sleep

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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.

PEEL CORNER TO READ COMPLETE DRUG FACTS AND INFORMATION

: 9W030 45 B2

Drug Facts (continued)

■ with any other product containing diphenhydramine, even one used on skin ■ 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
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■ be careful when driving a motor vehicle or operating machinery

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Drug Facts (continued)

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Other information ■ **each 20 mL contains:** sodium 7 mg ■ store at 20-25°C (68-77°F) ■ dosing cup provided ■ do not refrigerate

Inactive ingredients anhydrous citric acid, benzyl alcohol, edetate disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, triethyl citrate, xanthan gum

Questions or comments?
1-800-632-6900

NIGHT TIME COLD AND FLU

acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:30142-949
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 20 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	BLUE	**Score**	
Shape		**Size**	
Flavor	FRUIT	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:30142-949-30	180 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/22/2019	

Labeler - Kroger Company (006999528)

Revised: 4/2020 Kroger Company