MAXIMUM STRENGTH NIGHTTIME COLD AND FLU- acetaminophen, diphenhydramine hcl,phenylephrine hcl liquid THE KROGER CO

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.

Maximum Strength Nighttime Cold and Flu 6 fl oz. (180 mL)

Drug Facts

Active ingredients (in each 20 mL)	n Purposes	
Acetaminophen 650 mg	Pain reliever/fever reducer	
Diphenhydramine HCl 25 mg	Antihistamine/cough suppressant	
Phenylephrine HCl 10 mg	Nasal decongestant	

Uses

- temporarily relieves these common cold and flu symptoms:
 - cough
 - nasal congestion
 - minor aches and pains
 - 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 6 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Allergy alert: Acetaminophen may cause severe skin reactions .Symptoms may include:

- Skin reddening
- Blisters

rash

NaMs 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 drug containing diphenhydramine, even one used on the 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.

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
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, 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 fever, 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:

Taking more than the recommended dose (overdose) may cause liver damage. 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 6 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
- mL= milliliter
- 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 6 mg
- low sodium
- store at room temperature
- do not refrigerate
- dosing cup provided

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C blue #1, FD&C red #40, natural and artificial flavor, potassium citrate ,propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum.

Questions or comments?

1-888-287-1915

PRINCIPAL DISPLAY PANEL -

NDC# 30142-736-06

Compare to Mucinex $^{\circledR}$ Fast-Max $^{\circledR}$ Maximum Strength Might Time Cold & Flu Active Ingredients

Maximum Strength

Night TimeCold & Flu

Acetaminophen Pain Reliever/Fever Reducer Diphenhydramine HCl Antihistamine/Cough Suppressant Phenylephrine HCl Nasal Decongestant **Relieves:**

- Sore Throat; Itchy Throat-Cough
- Nasal Congestion Sneezing & Runny Nose
- Headache Body Pain

For Ages 12+

6 FL OZ (180 mL)

*This product is not manufactured or distributed by Reckitt Benckiser, the distributor of Mucinex® Fast- Max® Maximum Strength Nighttime Cold & Flu

Tamper evident: do not use if printed seal under cap is broken or missing.

‡Maximum Strength per 4 hour dose.

Distributed by:













MAXIMUM STRENGTH NIGHTTIME COLD AND FLU

acetaminophen, diphenhydramine hcl,phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-736
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
POTASSIUM CITRATE (UNII: EE90ONI6FF)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYL GALLATE (UNII: 8D4SNN7V92)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
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:30142-736- 06	180 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/04/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/04/2020	

Labeler - THE KROGER CO (006999528)

Revised: 8/2023 THE KROGER CO