# MAXIMUM STRENGTH NIGHTTIME COLD AND FLU- acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride liquid Wal-Mart Stores, Inc.,

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

## **Drug Facts**

Active ingredients (in each 20 mL)	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.

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 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.

for children under 12 years of age

# 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

you are 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 8 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# 49035-933-06

Compare to Mucinex<sup>®</sup> Fast-Max<sup>®</sup> Maximum Strength Severe Cold & Flu Active Ingredients\*

# Maximum Strength‡

#### Night TimeCold & Flu

**Acetaminophen** Pain Reliever/Fever Reducer Diphenhydramine HCl Antihistamine/Cough Suppressant Phenylephrine HCl Nasal Deongestant

# **Multi- Symptom Relief**

- Relieves Ache, Fever and Sore Throat
- Controls Cough
- Relieves Nasal Congestion
- · Relieves Runny Nose & Sneezing

# For Ages 12+

6 FL OZ (180 mL)

\*This product is not manufactured or distributed by Reckitt Benckiser, owner of the registered trademark Mucinex $^{\mathbb{R}}$  Fast- Max $^{\mathbb{R}}$  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: Walmart Inc.,

Bentonville, AR 72716











# MAXIMUM STRENGTH NIGHTTIME COLD AND FLU

acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-933
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	650 mg in 20 mL	
<b>DIPHENHYDRAMINE HYDRO CHLO RIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 20 mL	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL	

# **Inactive Ingredients**

Ingredient Name	Strength
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POTASSIUM CITRATE (UNII: EE90 O NI6 FF)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL GALLATE (UNII: 8 D4S NN7 V92)	
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		Imprint Code	
Contains			

ı	Packaging				
ı	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1	NDC:49035-933-06	180 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/02/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/02/2018	

# Labeler - Wal-Mart Stores, Inc., (051957769)

Revised: 1/2021 Wal-Mart Stores,Inc.,