

**MUCUS RELIEF COLD AND FLU DAYTIME/NIGHTTIME- acetaminophen, dextromethorphan hbr, diphenhydramine hcl, guaifenesin, phenylephrine hcl 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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**Equate 44-617694**

***Active ingredients (in each caplet) (Daytime Cold & Flu)***

Acetaminophen 325 mg  
Dextromethorphan HBr 10 mg  
Guaifenesin 200 mg  
Phenylephrine HCl 5 mg

***Purpose***

Pain reliever/fever reducer  
Cough suppressant  
Expectorant  
Nasal decongestant

***Active ingredients (in each caplet) (Nighttime Cold & Flu)***

Acetaminophen 325 mg  
Diphenhydramine HCl 12.5 mg  
Phenylephrine HCl 5 mg

***Purpose***

Pain reliever/fever reducer  
Antihistamine/cough suppressant  
Nasal decongestant

***Uses***

- temporarily relieves these common cold and flu symptoms:
  - headache
  - minor aches and pains
  - nasal congestion
  - cough
  - sore throat
  - sinus congestion and pressure
  - itching of the nose or throat **(Nighttime only)**
  - itchy, watery eyes due to hay fever **(Nighttime only)**

- runny nose and sneezing (**Nighttime only**)
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (**Daytime only**)
- controls cough to help you get to sleep
- temporarily reduces fever

## **Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- with other drugs containing acetaminophen
- more than 4,000 mg of acetaminophen in 24 hours
- 3 or more alcoholic drinks every day while using this product

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

- blisters
- rash
- skin reddening

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.
- 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
- with any other product containing diphenhydramine, even one used on skin (**Nighttime only**)

## **Ask a doctor before use if you have**

- heart disease
- thyroid disease
- diabetes
- liver disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

- a breathing problem such as emphysema or chronic bronchitis (**Nighttime only**)
- glaucoma (**Nighttime only**)

**Ask a doctor or pharmacist before use if you are**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (**Nighttime only**)

**When using this product**

- **do not exceed recommended dosage**
- excitability may occur, especially in children (**Nighttime only**)
- marked drowsiness may occur (**Nighttime only**)
- avoid alcoholic beverages (**Nighttime only**)
- alcohol, sedatives, and tranquilizers may increase drowsiness (**Nighttime only**)
- use caution when driving a motor vehicle or operating machinery (**Nighttime only**)

**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.**

In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Read each section carefully. Do not take DAYTIME and NIGHTTIME products at the same time.**

**Directions**

- **do not take more than directed**
- do not take more than 12 caplets in any 24-hour period
- adults and children 12 years and over: take 2 caplets every 4 hours
- children under 12 years: do not use

**Other information**

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

**Inactive ingredients (Daytime only)**

corn starch, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

**Inactive ingredients (Nighttime only)**

corn starch, croscarmellose sodium, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, iron oxide yellow, magnesium stearate, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium bicarbonate, stearic acid, talc, titanium dioxide

**Questions or comments?**

**1-800-426-9391**

**Principal display panel****Maximum Strength**

**equate™**

NDC 49035-358-01

Compare to Maximum  
Strength Mucinex®  
FAST-MAX® Day Time Cold & Flu  
and Night Time Cold & Flu Active ingredients\*

Daytime <b>Mucus Relief Cold &amp; Flu Acetaminophen-</b> Pain Reliever/Fever Reducer Dextromethorphan HBr Cough Suppressant Guaifenesin - Expectorant Phenylephrine HCl - Nasal Decongestant •Relieves headache, body pain, sore throat,	Nighttime Mucus Relief <b>Cold &amp; flu Acetaminophen -</b> Pain Reliever/Fever Reducer Diphenhydramine HCl - Antihistamine/ Cough Suppressant Phenylephrine HCl - Nasal Decongestant •Relieves headache, body pain, sore throat, fever, cough, itchy throat, nasal
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fever, cough, nasal & chest congestion & pressure	congestion, sneezing, runny nose
<b>20</b>	<b>10</b>
Daytime	Nighttime
Caplets	Caplets
Actual Size	Actual Size

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS  
OPENED OR IF BLISTER UNIT IS TORN, BROKEN  
OR SHOWS ANY SIGNS OF TAMPERING.**

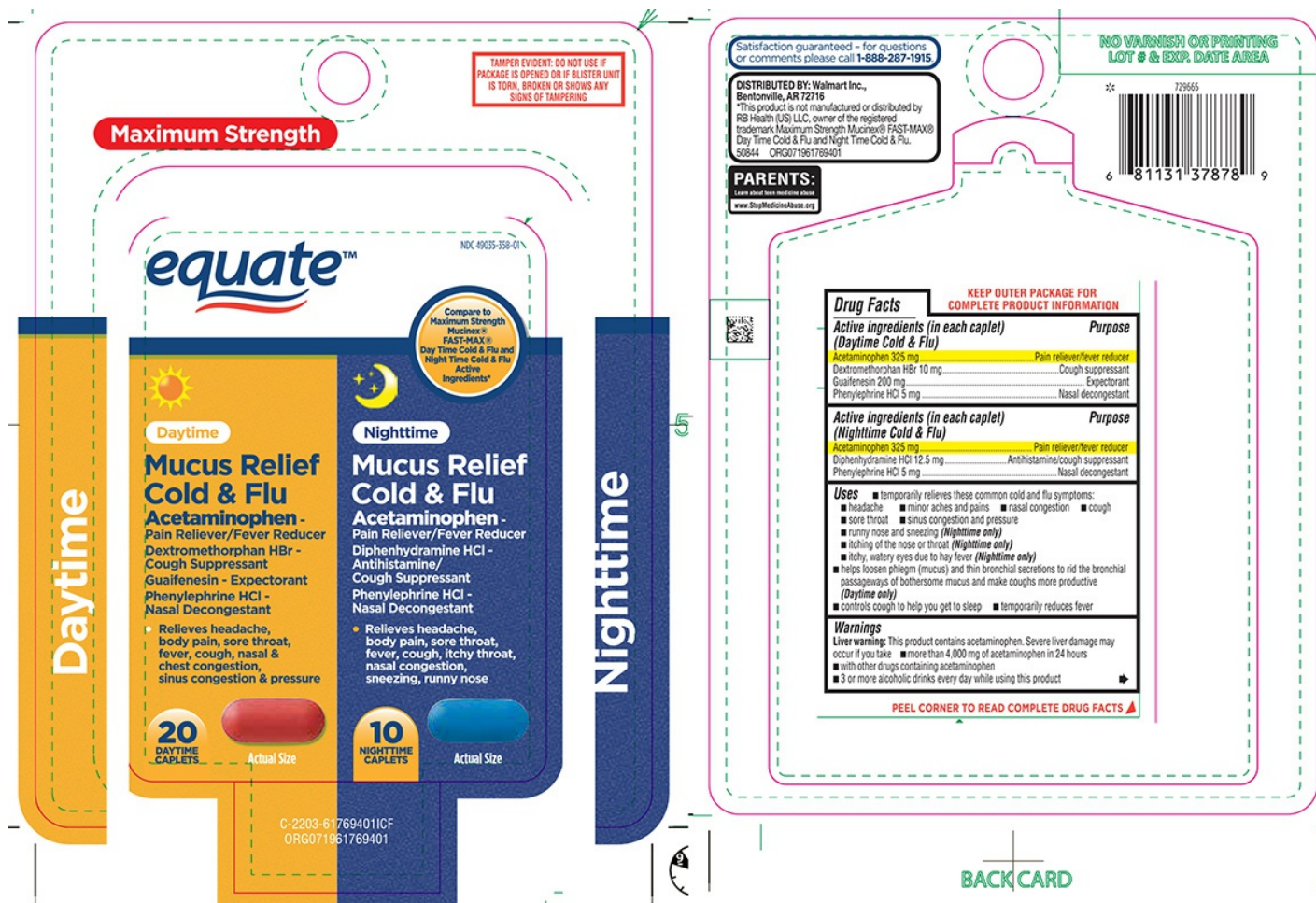
\*This product is not manufactured or distributed by RB Health (US) LLC, owner of the registered trademark Maximum Strength Mucinex<sup>®</sup> FAST-MAX<sup>®</sup> Day Time Cold & Flu and Night Time Cold & Flu.

50844 ORG071961769401

**DISTRIBUTED BY: Walmart Inc.  
Bentonville, AR 72716**

**PARENTS:  
Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)**

**Satisfaction Guaranteed - for questions or comments please call 1-888-287-1915.**



SAFE AREA 0.125"

#### Drug Facts (continued)

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include: blisters, rash, skin reddening. 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.
- 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.
- with any other product containing diphenhydramine, even one used on skin (Nighttime only)

#### Ask a doctor before use if you have

- heart disease
- thyroid disease
- diabetes
- liver disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis (Nighttime only)
- glaucoma (Nighttime only)

#### Drug Facts (continued)

**Ask a doctor or pharmacist before use if you are**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (Nighttime only)

#### When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children (Nighttime only)
- marked drowsiness may occur (Nighttime only)
- avoid alcoholic beverages (Nighttime only)
- alcohol, sedatives, and tranquilizers may increase drowsiness (Nighttime only)
- use caution when driving a motor vehicle or operating machinery (Nighttime only)

#### Stop use and ask a doctor if

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- redness or swelling is present
- new symptoms occur
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#### If pregnant or breast-feeding, ask a health professional before use.

**Keep out of reach of children.** In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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**Inactive ingredients (Nighttime only)** corn starch, croscarmellose sodium, croscopolone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, iron oxide yellow, magnesium stearate, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium bicarbonate, stearic acid, talc, titanium dioxide

**Questions or comments? 1-888-281-1915**

R-2203-617694-01-DCF  
50844 ORG071961769401

44-617694

## MUCUS RELIEF COLD AND FLU DAYTIME/NIGHTTIME

acetaminophen, dextromethorphan hbr, diphenhydramine hcl, guaifenesin, phenylephrine hcl kit

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:49035-358

### Packaging

Marketing Start

Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-358-01	1 in 1 PACKAGE; Type 0: Not a Combination Product	12/07/2020	
Quantity of Parts				
Part #	Package Quantity		Total Product Quantity	
Part 1	2 BLISTER PACK		20	
Part 2	1 BLISTER PACK		10	
Part 1 of 2				
MUCUS RELIEF COLD AND FLU DAYTIME				
acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated				
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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)			GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)			PHENYLEPHRINE HYDROCHLORIDE	5 mg
Inactive Ingredients				
Ingredient Name				Strength
STARCH, CORN (UNII: O8232NY3SJ)				
CROSPOVIDONE (UNII: 2S7830E561)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				

## Product Characteristics

Color	red	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	44;617
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		10 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	12/07/2020	

## Part 2 of 2

### MUCUS RELIEF COLD AND FLU NIGHTTIME

acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated

## Product Information

Route of Administration	ORAL
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## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>FD&amp;C BLUE NO. 1 ALUMINUM LAKE</b> (UNII: J9EQA3S2JM)	
<b>FD&amp;C BLUE NO. 2--ALUMINUM LAKE</b> (UNII: 4AQJ3LG584)	



<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I3O)	
<b>METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER</b> (UNII: NX76LV5T8J)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	44;694
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		10 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	12/07/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/07/2020	

**Labeler** - Wal-Mart Stores Inc (051957769)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(49035-358)

### Establishment

Name	Address	ID/FEI	Business Operations
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LNK International, Inc.		832867837	pack(49035-358)
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## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(49035-358)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(49035-358)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(49035-358)

Revised: 8/2021

Wal-Mart Stores Inc