# DAY SEVERE COLD AND NIGHT COLD AND FLU MAXIMUM STRENGTHacetaminophen, dextromethorphan hydrobromide, doxylamine succinate, guaifenesin, phenylephrine hydrochloride 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 Day Severe Cold and Night Cold and Flu

# Active ingredients (in each Softgel)

# **Day Severe Cold**

# Acetaminophen 325 mg

Dextromethorphan HBr 10 mg Guaifenesin 200 mg Phenylephrine HCl 5 mg

## Nighttime Cold & Flu

# Acetaminophen 325 mg

Dextromethorphan HBr 10 mg Doxylamine succinate 6.25 mg Phenylephrine HCl 5 mg

## **Purposes**

## **Day Severe Cold**

## Pain reliever/fever reducer

Cough suppressant Expectorant Nasal decongestant

# Nighttime Cold & Flu

## Pain reliever/fever reducer

Cough suppressant Antihistamine Nasal decongestant

## Uses

- temporarily relieves these common cold and flu symptoms:
  - cough
  - minor aches and pains
  - headache
  - nasal congestion
  - sore throat
  - 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 (*Nighttime only*)
- temporarily reduces fever

## **Warnings**

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

- more than 12 liquid gels in 24 hours, which is the maximum daily amount
- 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, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see 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.

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

# When using this product

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

## Stop use and ask a doctor if

nervousness, dizziness, or sleeplessness occur

- pain or nasal congestion 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:** 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. 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 12 softgels in any 24-hour period
- adults and children 12 years of age and older: take 2 softgels every 4 hours
- children under 12 years of age: do not use

## Other information

■ store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat.

## **Inactive ingredients**

**(Daytime only)** FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution and white ink

(**Nighttime only**) D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution and white ink

## Questions or comments?

Call toll free: **1-888-287-1915** 

## PRINCIPAL DISPLAY PANEL

Maximum Strength Day and Night Severe Cold & Flu Combo 24ct

NDC 49035-586-04

# DAY & NIGHT TWIN PACK



MAXIMUM STRENGTH Daytin

Severe Cold & Flu ACETAMINOPHEN 325mg

Dextromethorphan HBr 10mg Guaifenesin 200mg Phenylephrine HCI 5mg

HAXIMUM STRENGTH

Severe Cold & Flu

ACETAMINOPHEN 325mg Destromethorphen HBr 10mg Daxylamine succinate 6.25mg Phenylephrine HCI 5mg

eauate™

NDC 49035-586-04

Compare to Mucinex® Fast-Max® Day Severe Cold and **Night Cold** & Flu Active Ingredients<sup>1</sup>

\*\*Per 4-hour dose

Do not take the Day Severe Cold and Night Cold & Flu softgels at the same time. Do not take more than a total of 12 softgels in a 24-hour period.

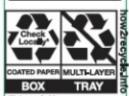
Do not take the first dose of the Night Cold & Flu softgels sooner than 4 hours after the last dose of the Day Severe Cold softgels unless directed by a doctor.

Take only as directed.

Keep carton for complete product information

# PARENTS

www.StopMedicineAbuse.org



# Maximum Strength\*\*

**Fast Dissolving Softgels** 

# Severe Cold & Flu

# ACETAMINOPHEN

Pain Reliever / Fever Reducer Dextromethorphan HBr Cough Suppressant

Gualfenesin

Phenylephrine HCI Nasal Decongestant

- Relieves nasal & chest congestion Thins & loosens mucus



# Day Severe Cold Night Cold & Flu

ACETAMINOPHEN Pain Reliever / Fever Reducer

Dextromethorphan HBr Cough Suppressant

Doxylamine succinate Antihistamine

Phenylephrine HCI Nasal Decongestant

- Relieves aches, fever & sore throat
- Controls cough
- Relieves nasal congestion
- Relieves runny nose & sneezing



Actual Size

16 SOFTGELS (Liquid Filled Capsules)

24 TOTAL

8 SOFTGELS (Liquid Filled Capsules) lamper evident: Do not use if carlon is damaged or if printed seal on blister is broken or missing.

DISTRIBUTED BY: Walmart Inc. Bentomille, AR 72716 PRODUCT OF CHINA "This product is not manufactured or distribute by Recklitt Bendisser LLC, owner of the registered trademarks Mucines® Fast-Max®

Day Severe Cold and Night Cold & Flu.

Satisfaction guaranteed - For questions or comments please call 1-888-287-1915

WM23-00

## Drug Facts

Active ingredients (in each Softgel) Daytime Severe Cold

Acetaminophen 325 mg.....Pain reliever/fever reducer
Dextromethorphan HBr 10 mg.....Cough suppressant Guaifenesin 200 mg......Expectorant ..Nasal decongestant Phenylephrine HCl 5 mg.....

Active ingredients (in each Softgel) Purposes Niahttime Cold & Flu

Acetaminophen 325 mg......Pain reliever/fever reducer Dextromethorphan HBr 10 mg......................Cough suppressant Doxylamine succinate 6.25 mg..... ....Antihistamine Phenylephrine HCl 5 mg.......Nasal decongestant

USES = temporarily relieves these common cold and flu symptoms:

- minor aches and pains ■ cough
- headache nasal congestion sore throat
- runny nose and sneezing (Nighttime only)
- helps loosen phiegm (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 (Nighttime only)
- temporarily reduces fever

### Warnings

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

- more than 12 softgets 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.

 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

- Iver disease heart disease diabetes
- high blood pressure thyroid disease
- trouble urinating due to an enlarged prostate gland
- glaucoma (Nighttime only)

## Drug Facts (continued)

Purposes

- breathing problems such as emphysema or chronic bronchitis (Nighttime only) persistent or chronic cough such as occurs with smoking,
- asthma, chronic bronchitis, or emphysema

cough that occurs with too much phiegm (mucus)

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 use more than directed
- excitability may occur, especially in children (Nighttime only)
- marked drowsiness may occur (Nighttime only) alcohol, sedatives, and tranquilizers may increase drowsiness (Nighttime only)
- avoid alcoholic drinks (Nighttime only)
- be careful 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.

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. 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 12 softgels in any 24-hour period
- adults and children 12 years of age and older: take 2 softgels every 4 hours
- children under 12 years of age: do not use

Other information ■ store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat.

Inactive ingredients (Daytime only) FD&C yelow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, and white ink (Nighttime only) D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water,

Questions or comments? 1-888-287-1915

sorbitol sorbitan solution, and white ink

## DAY SEVERE COLD AND NIGHT COLD AND FLU MAXIMUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, guaifenesin, phenylephrine hydrochloride kit

## **Product Information**

HUMAN OTC DRUG NDC:49035-586 Item Code (Source) Product Type

I	Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
1	NDC:49035-586-04	1 in 1 CARTON; Type 0: Not a Combination Product	0 1/3 1/2 0 18			

Quantity of Parts					
Part # Package Quantity		Total Product Quantity			
Part 1	2 BLISTER PACK	16			
Part 2	1 BLISTER PACK	8			

# Part 1 of 2

# DAY SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride capsule, liquid filled

## **Product Information**

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>DEXTRO METHO RPHAN HYDRO BRO MIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTRO METHO RPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg		
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		

Inactive Ingredients		
Ingredient Name	Strength	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)		
PO VIDO NE (UNII: FZ989 GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SORBITOL (UNII: 506T60A25R)		
SORBITAN (UNII: 6 O 9 2 ICV 9 RU)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics				
Color ORANGE (clear) Score no score				
Shape	CAPSULE (Oblong)	Size	25mm	
Flavor		Imprint Code	PC26	
Contains	Contains			

# **Packaging**

#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1		2 in 1 CARTON		
1		8 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	0 1/3 1/2 0 18		

# Part 2 of 2

# NIGHT SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

## **Product Information**

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	325 mg		
<b>DEXTRO METHO RPHAN HYDRO BRO MIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTRO METHO RPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg		
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg		
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		

Inactive Ingredients		
Ingredient Name	Strength	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)		
PO VIDO NE (UNII: FZ989 GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SORBITOL (UNII: 506T60A25R)		
SORBITAN (UNII: 6 O92ICV9RU)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics				
Color green (clear) Score no score				
Shape	CAPSULE (Oblong)	Size	21mm	

C	ontains					
P	Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date		
1		1 in 1 CARTON				
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product				

Imprint Code

PC22

Marketing Information				
Marketing Category	Marketing End Date			
OTC monograph final	part341	0 1/3 1/20 18		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part341	0 1/3 1/2 0 18			

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

Flavor

Establishment						
Name	Address	ID/FEI	Business Operations			
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(49035-586), analysis(49035-586)			

Revised: 3/2019 Wal-Mart Stores, Inc.