

**DAY SEVERE COLD NIGHT COLD AND FLU- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl, doxylamine succinate**  
**Rite Aid Corporation**

*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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**Rite Aid Corporation Day Severe Cold Night Cold & Flu Drug Facts**

**Active ingredients (in each liquid gel) – DAY Severe Cold**

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

**Purposes – DAY Severe Cold**

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

**Active ingredients (in each liquid gel) – NIGHT Cold & Flu**

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

**Purposes – NIGHT 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 (NIGHT only)
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (DAY only)
- controls cough to help you get to sleep (NIGHT only)
- temporarily reduces fever

## **Warnings**

Liver warning: These products contain 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 these products

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 these products.
- if you have ever had an allergic reaction to these products or any of their ingredients

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

**When using these products**

- do not use more than directed
- excitability may occur, especially in children (NIGHT only)
- marked drowsiness may occur (NIGHT only)
- alcohol, sedatives, and tranquilizers may increase drowsiness (NIGHT only)
- avoid alcoholic drinks (NIGHT only)
- be careful when driving a motor vehicle or operating machinery (NIGHT 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: 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 10 liquid gels in any 24-hour period
- adults and children 12 years of age and older: take 2 liquid gels every 4 hours
- children under 12 years of age: do not use

**Other information**

- store at 20-25°C (68-77°F)

**Inactive ingredients (DAY only)**

edible ink\*, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone,

propylene glycol, purified water, sorbitol sorbitan solution \*may contain this ingredient

**Inactive ingredients (NIGHT only)**

D&C yellow #10, edible ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution

**Questions or comments?**

1-800-719-9260

**Package/Label Principal Display Panel**

COMBO PACK

Compare to the active ingredients of Mucinex® Fast-Max® Day Severe Cold & Mucinex® Fast-Max® Night Cold & Flu

fast dissolving liquid gels

MAXIMUM STRENGTH

daytime

day

severe cold

acetaminophen

dextromethorphan HBr

guaifenesin

phenylephrine HCl

pain reliever/fever reducer

cough suppressant

expectorant

nasal decongestant

relieves aches, fever & sore throat

controls cough

relieves nasal & chest congestion

thins & loosens mucus

ACTUAL SIZE

16 LIQUID GELS

(liquid filled capsules)

24 TOTAL for ages 12+

MAXIMUM STRENGTH

nighttime

night

cold & flu

acetaminophen

dextromethorphan HBr

doxylamine succinate

phenylephrine

pain reliever/fever reducer

cough suppressant

antihistamine

nasal decongestant

relieves aches, fever & sore throat

controls cough

relieves nasal congestion

relieves runny nose & sneezing

ACTUAL SIZE

24 TOTAL

for ages 12+

8 LIQUID GELS

(liquid filled capsules)



# COMBO PACK

\*\*Compare to the active ingredients of Mucinex® Fast-Max® Day Severe Cold & Mucinex® Fast-Max® Night Cold & Flu

PHARMACY

fast dissolving liquid gels

MAXIMUM STRENGTH†

## daytime day severe cold

**acetaminophen**  
dextromethorphan HBr  
guaifenesin  
phenylephrine HCl

pain reliever/fever reducer  
cough suppressant  
expectorant  
nasal decongestant

relieves aches, fever & sore throat  
controls cough  
relieves nasal & chest congestion  
thins & loosens mucus



ACTUAL SIZE

**16 LIQUID GELS**  
(liquid filled capsules)

**24 TOTAL**  
for ages 12 +

MAXIMUM STRENGTH†

## nighttime night cold & flu

**acetaminophen**  
dextromethorphan HBr  
doxylamine succinate  
phenylephrine HCl

pain reliever/fever reducer  
cough suppressant  
antihistamine  
nasal decongestant

relieves aches, fever & sore throat  
controls cough  
relieves nasal congestion  
relieves runny nose & sneezing



ACTUAL SIZE

**8 LIQUID GELS**  
(liquid filled capsules)

DISTRIBUTED BY:  
RITE AID  
30 HUNTER LANE  
CAMP HILL, PA 17011  
MADE IN CANADA



RA# 0368598





# nighttime cold & flu

MAXIMUM  
STRENGTH†

# daytime severe cold

MAXIMUM  
STRENGTH†

fast dissolving liquid gels

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN



## Drug Facts

### Active ingredients (in each liquid gel) DAY Severe Cold

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

### Active ingredients (in each liquid gel) NIGHT 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

### Purposes

**Uses** ■ temporarily relieves these common cold and flu symptoms: ■ cough ■ minor aches and pains  
■ headache ■ nasal congestion ■ sore throat  
■ runny nose and sneezing (**NIGHT only**)  
■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (**DAY only**)  
■ controls cough to help you get to sleep (**NIGHT only**)  
■ temporarily reduces fever

### Warnings

**Liver warning:** These products contain 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 these products

**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 these products. ▶

## Drug Facts (continued)

■ if you have ever had an allergic reaction to these products or any of their ingredients

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

### When using these products

- do not use more than directed
- excitability may occur, especially in children (**NIGHT only**)
- marked drowsiness may occur (**NIGHT only**)
- alcohol, sedatives, and tranquilizers may increase drowsiness (**NIGHT only**)
- avoid alcoholic drinks (**NIGHT only**)
- be careful when driving a motor vehicle or operating machinery (**NIGHT 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:** 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 10 liquid gels in any 24-hour period
- adults and children 12 years of age and older: take 2 liquid gels every 4 hours
- children under 12 years of age: do not use

### Other information

- store at 20-25°C (68-77°F) ▶

## Drug Facts (continued)

### Inactive ingredients (DAY only)

edible ink\*, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution  
\*may contain this ingredient

### Inactive ingredients (NIGHT only)

D&C yellow #10, edible ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution

### Questions or comments?

1-800-719-9260

\*\*These products are not manufactured or distributed by Reckitt Benckiser, distributor of Mucinex® Fast-Max® Day Severe Cold & Mucinex® Fast-Max® Night Cold & Flu.

†Per 4-hour dose, dose every 4 hours

Do not take DAY Severe Cold and NIGHT Cold & Flu liquid gels at the same time. Do not take more than a total of 10 liquid gels in a 24-hour period.

Do not take the first dose of the NIGHT Cold & Flu liquid gels sooner than 4 hours after the last dose of the DAY Severe Cold liquid gels unless directed by a doctor.

Take only as directed

Keep carton for complete product information.

**PARENTS:**

Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)





6U090 83 C2

**DAY SEVERE COLD NIGHT COLD AND FLU**

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl, doxylamine succinate kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-0717
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**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0717-0	1 in 1 KIT; Type 0: Not a Combination Product	06/28/2017	

**Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1		16
Part 2		8

**Part 1 of 2****DAY SEVERE COLD**

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule, liquid filled

**Product Information**

<b>Route of Administration</b>	ORAL
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**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
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FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

### Product Characteristics

Color	ORANGE	Score	no score
Shape	CAPSULE	Size	25mm
Flavor		Imprint Code	7G0
Contains			

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341		

### Part 2 of 2

### NIGHT COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl capsule, liquid filled

### Product Information

Route of Administration	ORAL
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### 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
DOXYLAMINE SUCCINATE (UNII: V9B19B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (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: HBR47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	

<b>POLYETHYLENE GLYCOL</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0K00R)	

**Product Characteristics**

<b>Color</b>	GREEN	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	345
<b>Contains</b>			

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/28/2017	

**Labeler** - Rite Aid Corporation (014578892)