DAYTIME MUCUS RELIEF SEVERE CONGESTION AND COUGH AND NIGHTTIME COLD AND FLU MAXIMUM STRENGTH- dextromethorphan hbr, guaifenesin, phenylephrine hci, acetaminophen, diphenhydramine hci
Walgreens

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.

DRUG FACTS

Active ingredients for Nighttime (in each 20 mL)

Acetaminophen 650 mg

Diphenhydramine HCl 25 mg

Phenylephrine HCl 10 mg

Active ingredients for Daytime (in each 20 mL)

Dextromethorphan HBr 20 mg

Guaifeenesin 400 mg

Phenylephrine HCl 10 mg

Purpose for Nighttime

Pain reliever/fever reducer

Antihistamine/cough suppressant

Nasal decongestant

Purpose for Daytime

Cough suppressant

Expectorant

Nasal decongestant

Uses

Nighttime

- 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

Daytime
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageway of bothersome mucus and make coughs more productive
- temporarily relieves
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - the impulse to cough to help you get to sleep
  - nasal congestion due to a cold

Warnings

NIGHTTIME

Liver warning: This product 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 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

Nighttime
- with any 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

Daytime

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI)(certain drugs for depression,psychiatic 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

Nighttime

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to an enlarged prostate gland
- 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)

Daytime

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphtsema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are

Nighttime

- taking the blood thinning drug warfarin
- taking sedative or tranquilizers

When using these products

Nighttime

- **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 vehicile or operating machinery

Daytime

- **do not use more than directed**

Stop use and ask a doctor if

Nighttime

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse, or lasts more than 7 days
- fever gets worse, or last 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 a signs of a serious condition

Daytime

- nervousness, dizziness or sleeplessness occur
- symptoms do not get better within 7 days or occur with fever
- cough comes back, or occur with fever, rash, or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding,

Nighttime

ask a health professional before use.

Daytime

ask a health professional before use

Keep out of reach of children.

Nighttime

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 (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Daytime

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

Nighttime

- **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 any other dosing device
- keep dosing cup with product
- mL = milliliter
- dose as follows or as directed by a doctor
- adults and children 12 years and older: 20 mL every 4 hours while symptoms last
- children under 12 years of age: do not use

Daytime

- do not take more than 6 doses in any 24-hours period
- measure only with dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product
- mL = milliliter
- shake well before using
- 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

Nighttime

- **each 20 mL contains**: sodium 12 mg
- store between 20-25ºC (68-77ºF). Do not refrigerate.

Daytime

- **each 20 mL contains**: 17 mg
- store between 20-25ºC (68-77ºF). Do not refrigerate.

Inactive ingredients

Nighttime

citric acid, disodium EDTA, FD&C Blue #1, FD&C red #40, Flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

Daytime

citric acid, disodium EDTA, FD&C blue #1, FD&C red #40, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

Questions or comments?

Nighttime

Call **1-877-753-3935 Monday- Friday 9AM- 5PM EST**

Daytime

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to Maximum Strength Mucinex® Fast-Max® Severe Congestion & Cough & Night Time Cold & Flu active ingredient††

NIGHTTIME

Cold & Flu

ACETAMINOPHEN /

PAIN RELIEVER & FEVER REDUCER

DIPHENHYDRAMINE HCl /

ANTIHISTAMINE / COUGH SUPPRESSANT

PHENYLEPHRINE HCl /

NASAL DECONGESTANT

MAXIMUM STRENGTH

- Relieves aches, fever, sore throat, nasal congestion, runny nose, & sneezing
- Controls cough
- For ages 12 & over

DAYTIME

Severe Congestion & Cough

DEXTROMETHORPHAN HBr /

COUGH SUPPRESSANT

GUAIFENESIN / EXPECTORANT

PHENYLEPHRINE HCl / NASAL DECONGESTANT

MAXIMUM STRENGTH

- Controls Cough
- Clears nasal & chest congestion
- Thins & loosens mucus
- For ages 12 & over

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND OR UNDER CAP IS BROKEN OR MISSING.

††This product is not manufactured or distributed by Reckitt Benckiser, distributor of Maximum Strength Mucinex® FAST-MAX® Severe Congestion & Cough & Nighttime Cold & Flu.

DISTRIBUTED BY: WALGREEN **CO.**

200 WILMOT RD., DEERFIELD, IL 60015

walgreens.com

Product Label

WALGREENS Daytime Severe Congestion & Cough Nighttime Cold & Flu

DAYTIME MUCUS RELIEF SEVERE CONGESTION AND COUGH AND NIGHTTIME COLD AND FLU MAXIMUM STRENGTH

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

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-0862

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0862-12	1 in 1 KIT; Type 0: Not a Combination Product	07/31/2015	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	177 mL
Part 2	1 BOTTLE, PLASTIC	177 mL

Part 1 of 2

MUCUS RELIEF SEVERE CONGESTION AND COUGH MAXIMUM STRENGTH

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid

Product Information

Item Code (Source)	NDC:0363-0337
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0363-0337-06	177 mL in 1 BOTTLE, PLASTIC; 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	07/31/2015	

Part 2 of 2

NIGHTTIME COLD AND FLU MAXIMUM STRENGTH

acetaminophen, diphenhydramine hci, phenylephrine hci liquid

Product Information	
Item Code (Source)	NDC:0363-0460

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	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
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0460-06	177 mL in 1 BOTTLE, PLASTIC; 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	07/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/31/2015	

Labeler - Walgreens (008965063)

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