DAYTIME MUCUS RELIEF SEVERE COLD AND NIGHTTIME COLD AND FLU MAXIMUM STRENGTH- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl,guaifenesin
Safeway, 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.

Drug Facts

Active ingredients in Daytime (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Active ingredients in Nighttime (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

Purpose for Daytime

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Purpose for Nighttime

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

DAYTIME

- temporarily relieves these common cold and flu symptoms
  - headache
  - nasal congestion
  - sore throat
  - cough
  - minor aches and pains
  - helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
  - temporarily reduces fever

NIGHTTIME

- temporarily relieves these common cold and flu symptoms
  - cough
  - headache
  - minor aches and pains
  - sore throat
  - nasal congestion
  - runny nose and sneezing
  - controls cough to help you get to sleep
  - temporarily reduces fever

Warnings

DAYTIME and NIGHTTIME

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 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

DAYTIME and NIGHTTIME

- 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

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

NIGHTTIME
- liver disease
- diabetes
- high blood pressure
- heart disease
- glaucoma
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic cough
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma chronic bronchitis or emphysema

Ask a doctor or pharmacist before use if you are

DAYTIME

taking the blood thinning drug warfarin

NIGHTTIME

taking the blood thinning drug warfarin

taking sedatives or tranquilizers

When using this product,

DAYTIME

do not use more than directed

NIGHTTIME
- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur

- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

DAYTIME and NIGHTTIME

- 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 coukld be signs of a serious condition.

If pregnant or breast-feeding,

DAYTIME and NIGHTTIME

ask a health professional before use.

Keep out of reach of children.

DAYTIME and NIGHTTIME

Overdose warning: Taking more than the recommended dose can 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.

Directions

DAYTIME

- do not take more than directed (see Overdose warning)
- do not take more than 12 softgels (Daytime and NightTime) 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
- when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing

NIGHTTIME

- do not take more than directed (see Overdose warning)
- do not take more than 12 softgels (Daytime and Nighttime) 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
- when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing

Other information

DAYTIME and **NIGHTTIME**

- swallow whole; do not crush, chew, or dissolve
- store between 20-25ºC (68-77ºF**)**
- avoid excessive heat

Inactive ingredients

DAYTIME

FD&C red #40, FD&C yellow #6, gelatin, glycerin, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide

NIGHTTIME

D&C yellow #10, FD&C blue #1, gelatin, glycerin, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide

Questions or comments?

DAYTIME and NIGHTTIME

Call **1-877-723-3935** Monday-Friday 79M-5PM EST

Principal Display Panel

Compare to the active ingredients in Maximum Strength Mucinex® Fast-Max® Day Severe Cold & Night Cold & Flu†

MAXIMUM STRENGTH

DAY TIME

Mucus Relief Severe Cold

Acetaminophen - 325 mg Pain Reliever / Fever Reducer

Dextromethorphan HBr - 10 mg Cough Suppressant

Guaifenesin - 200 mg Expectorant

Phenylephrine HCI - Nasal Decongestant
- Relieves aches, fever & sore throat
- Controls cough
- Relieves nasal & chest congestion
- thins & loosens mucus

SOFTGELS**

(**Liquid-filled capsules)

MAXIMUM STRENGTH

NIGHT TIME

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

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

SOFTGELS**

(**Liquid-filled capsules)

*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Maximum Strength Mucinex® Fast-Max® Day Severe Cold and Maximum Strength Mucinex® Fast-Max® Night Cold & Flu.

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

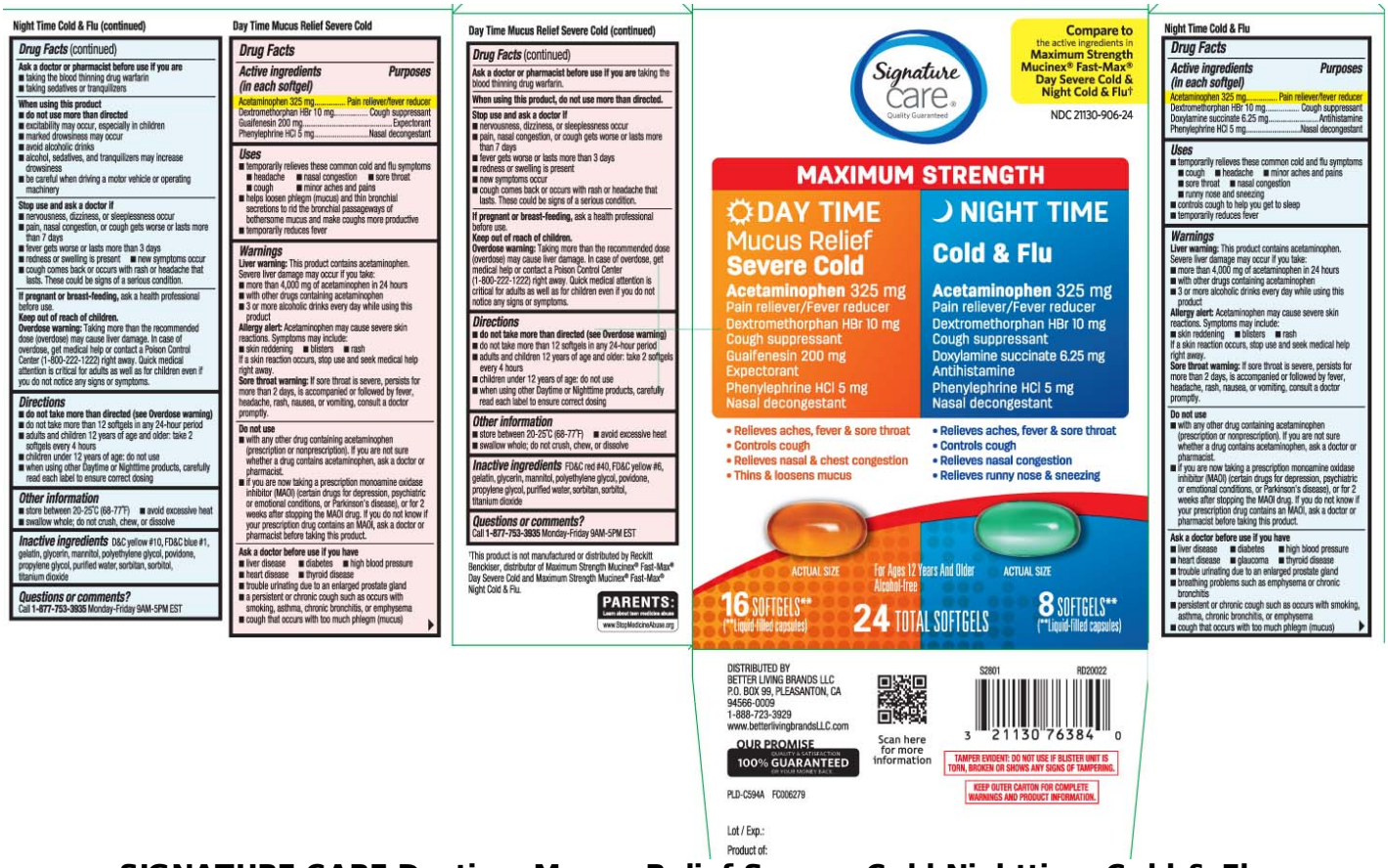
DISTRIBUTED BY

BETTER LIVING BRANDS LLC

P.O. BOX 99, PLEASANTON, CA 94566-0009

www.betterlivingbrandsLLC.com

Product Label



SIGNATURE CARE Daytime Mucus Relief Severe Cold Nighttime Cold & Flu

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

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-906

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-906-24	1 in 1 KIT; Type 0: Not a Combination Product	01/31/2020	02/28/2025

Quantity of Parts

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

Part 1 of 2

NIGHTTIME COLD AND FLU MAXIMUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hci capsule

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
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (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: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics

Color	green	**Score**	no score
Shape	CAPSULE	**Size**	20mm
Flavor		**Imprint Code**	42A
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 in 1 CARTON		
1		1 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	01/31/2020	02/28/2025

Part 2 of 2

DAYTIME MUCUS RELIEF SEVERE COLD MAXIMUM STRENGTH DAYTIME

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hci capsule

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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics

Color	orange	**Score**	no score
Shape	CAPSULE	**Size**	20mm

Flavor		**Imprint Code**	12A
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		16 in 1 CARTON		
1		1 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	01/31/2020	02/28/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/31/2020	02/28/2025

Labeler - Safeway, Inc. (009137209)

Revised: 11/2022 Safeway, Inc.