UP AND UP DAYTIME SEVERE COLD NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl, diphenhydramine hcl Target 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.

Target Corporation Daytime Severe Cold Nighttime Cold and Flu Drug Facts

Active ingredients (in each caplet) - DAY TIME Severe Cold

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

Active ingredients (in each caplet) – NIGHT TIME Cold & Flu

Acetaminophen 325 mg Diphenhydramine HCl 25 mg Phenylephrine HCl 5 mg

Purposes - DAY TIME Severe Cold

Pain reliever/fever reducer Cough suppressant Expectorant Nasal decongestant

Purposes - NIGHT TIME Cold & Flu

Pain reliever/fever reducer Antihistamine Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
- nasal congestion
- cough (DAY TIME Severe Cold only)
- minor aches and pains
- headache
- sore throat
- runny nose and sneezing (NIGHT TIME Cold & Flu only)
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (DAY TIME Severe Cold 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.
- with any other product containing diphenhydramine, even one used on skin (NIGHT TIME Cold & Flu only)
- 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
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- glaucoma (NIGHT TIME Cold & Flu only)
- a breathing problem such as emphysema or chronic bronchitis (NIGHT TIME Cold & Flu only)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema (DAY TIME Severe Cold only)
- cough that occurs with too much phlegm (mucus) (DAY TIME Severe Cold only)

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (NIGHT TIME Cold & Flu only)

When using these products

- do not use more than directed
- excitability may occur, especially in children (NIGHT TIME Cold & Flu only)
- marked drowsiness may occur (NIGHT TIME Cold & Flu only)
- alcohol, sedatives, and tranquilizers may increase drowsiness (NIGHT TIME Cold & Flu only)
- avoid alcoholic drinks (NIGHT TIME Cold & Flu only)
- be careful when driving a motor vehicle or operating machinery (NIGHT TIME Cold & Flu 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. (DAY TIME Severe Cold only)

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

Other information

- each caplet contains: sodium 4 mg (DAY TIME Severe Cold only)
- store at 20-25°C (68-77°F)

Inactive ingredients (DAY TIME Severe Cold)

croscarmellose sodium, crospovidone, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone,

pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

Inactive ingredients (NIGHT TIME Cold & Flu)

crospovidone, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

Questions?

Call 1-888-547-7400

Principal Display Panel

Compare to active ingredients in Mucinex® Fast-Max® Day Time Severe Cold

see new warnings

maximum strength

daytime severe cold

acetaminophen (pain reliever/fever reducer)

dextromethorphan HBr (cough suppressant)

guaifenesin (expectorant)

phenylephrine HCl (nasal decongestant)

relieves headache, fever and sore throat

relieves nasal and chest congestion

controls cough

thins and loosens mucus

ACTUAL SIZE

AGES 12+ YEARS

20 CAPLETS

Compare to active ingredients in Mucinex® Fast-Max® Night Time Cold & Flu

see new warnings

maximum strength

nighttime cold and flu

acetaminophen (pain reliever/fever reducer)

diphenhydramine HCl (antihistamine)

phenylephrine HCL (nasal decongestant)

relieves headache, fever and sore throat

relieves nasal congestion

relieves sneezing and runny nose

ACTUAL SIZE

AGES 12+ YEARS

10 CAPLETS

see new warnings

maximum strength** **daytime** severe cold

acetaminophen

(pain reliever/fever reducer) dextromethorphan HBr (cough suppressant) guaifenesin (expectorant) phenylephrine HCl (nasal decongestant)

relieves headache, fever and sore throat

relieves nasal and chest congestion controls cough thins and loosens mucus

up&up

ACTUAL SIZE

AGES

see new warnings

maximum strength** **nighttime cold and flu**

acetaminophen

(pain reliever/fever reducer) diphenhydramine HCI (antihistamine) phenylephrine HCI (nasal decongestant)

relieves headache, fever and sore throat

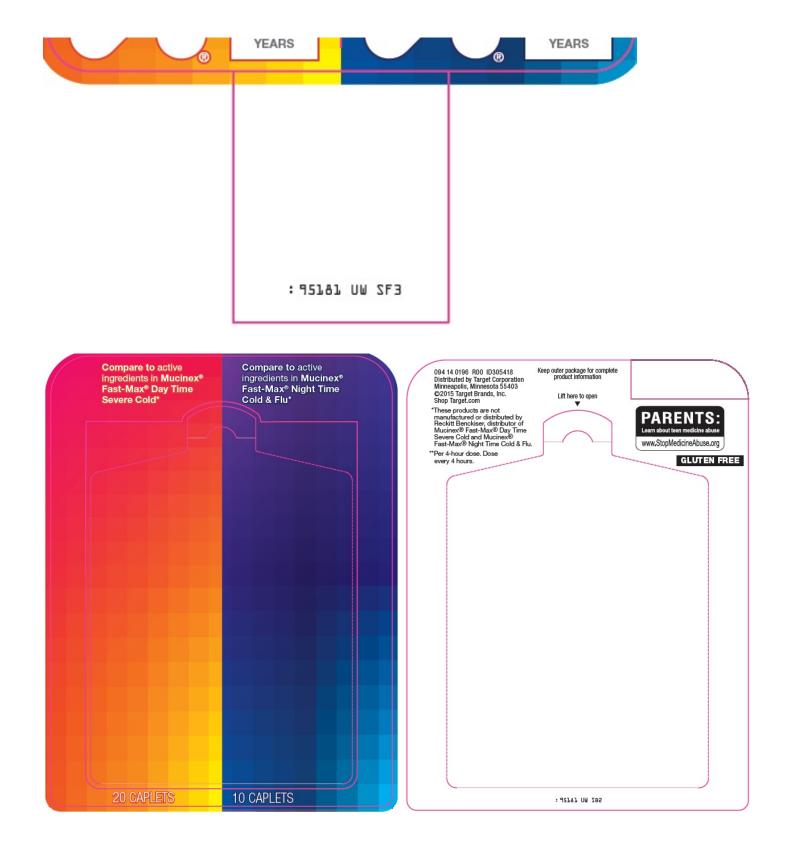
relieves nasal congestion

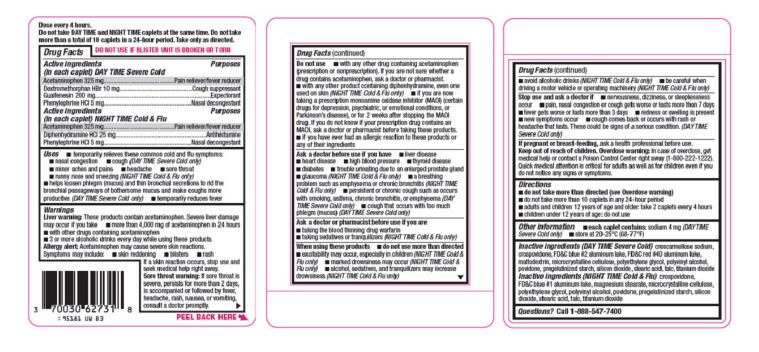
relieves sneezing and runny nose

up&up

ACTUAL SIZE

AGES





UP AND UP DAYTIME SEVERE COLD NIGHTTIME COLD AND FLU

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

Product Information							
Product T ype		HUMAN O	TC DRUG	Item Code (Source)		NDC:11673-837	
Packa	iging						
# I	tem Code	P	ackage Description		Marketing Start Date	Marketing End Date	
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Quant	tity of Parts						
Part #		Package Qua	intity		Total Product Qu	antity	
Part 1	10 BLISTER PA	СК		20			
Part 2	5 BLISTER PAC	К		10			
Part	1 of 2						
UP A	ND UP D	AYTIME	SEVERE COLI	D			
acetan	ninophen, dex	tromethorpha	n hbr, guaifenesin, p	henvlephrin	e hcl tablet, film coated		
acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated							
Product Information							
Route	of Administrat	ion	ORAL				
Active Ingredient/Active Moiety							

DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9KYH)DEXTROMETHORPHAN HYDROBROMIDE10 mg(DEXTROMETHORPHAN - UNII:7355X3ROTS)GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)GUAIFENESIN200 mgPHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -PHENYLEPHRINE5 mg			Ingredient Name			Basis of S	trength	Strengt	
(DEXTROMETHORPHAN. UNIX-235X3075) HYDROBROMIDE 200 m GUALFENESIN (UNIX-495W7451VQ) (GUALFENESIN - UNIX-495W7451VQ) GUALFENESIN 200 m PIENYLEPINNE HYDROCHLORDE (UNIX-04/A59TNS)) (PIENYLEPIRNE) - PIENYLEPINNE 3 mg Ingredient Same Strength	ACETAMINO PH	IEN (UNII: 362	209ITL9D) (ACETAMINOPHE	N - UNII:36209ITL	9D)	ACETAMINOPHE	N	325 mg	
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Ingredient Name Strength CROSPOVIDONE (15 MPA.S AT 5%) (UNIE 68401660MK) <						Ξ	5 mg		
CROSCARMELLOSE SODIUM (UNIE M2801/III148)	Inactive Ing	redients							
CROSPO VIDONE (15 MPA.S AT 5%) (UNI: 6840 1960 MR)			0	Name			5	strength	
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MICRO CRYSTALLINE CELLULOSE (UNII: OPIR32D61U) Image: Content of the second of th		•		.)					
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Route of Administration

ORAL

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg			
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg			
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg			

Inactive Ingredients				
Ingredient Name	Strength			
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL (UNII: 532B59J990)				
POVIDONE (UNII: FZ989GH94E)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				

Product Characteristics

Color	BLUE	Score	no score
Shape	CAPSULE	Size	16 mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		5 in 1 PACKAGE		
1		2 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		

Marketing Information

Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date

Labeler - Target Corporation (006961700)

Revised: 12/2019

Target Corporation