

**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.*

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**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



ACTUAL SIZE

AGES

**12+**

**up&up**

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

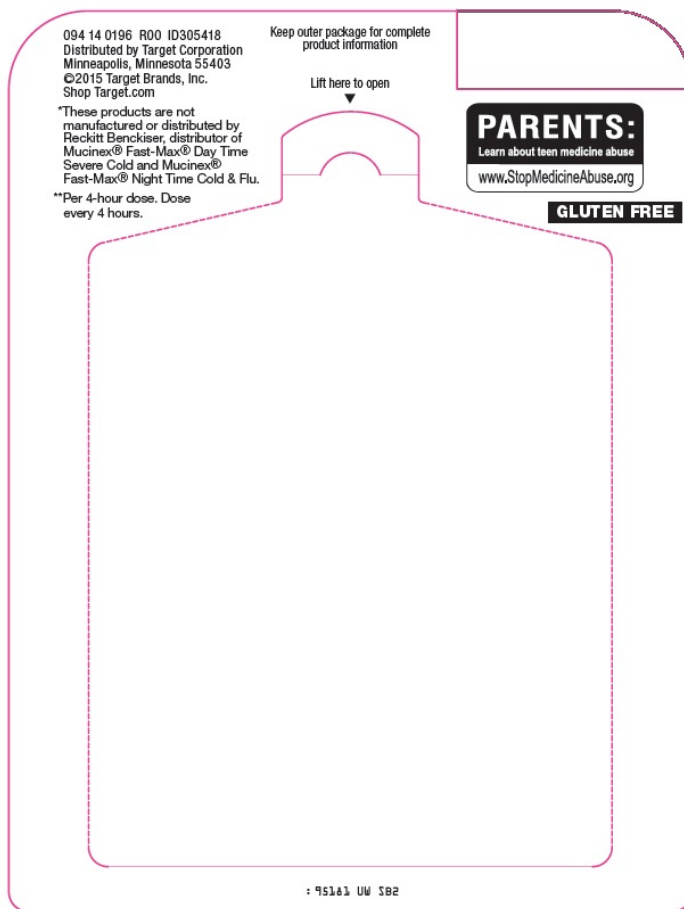
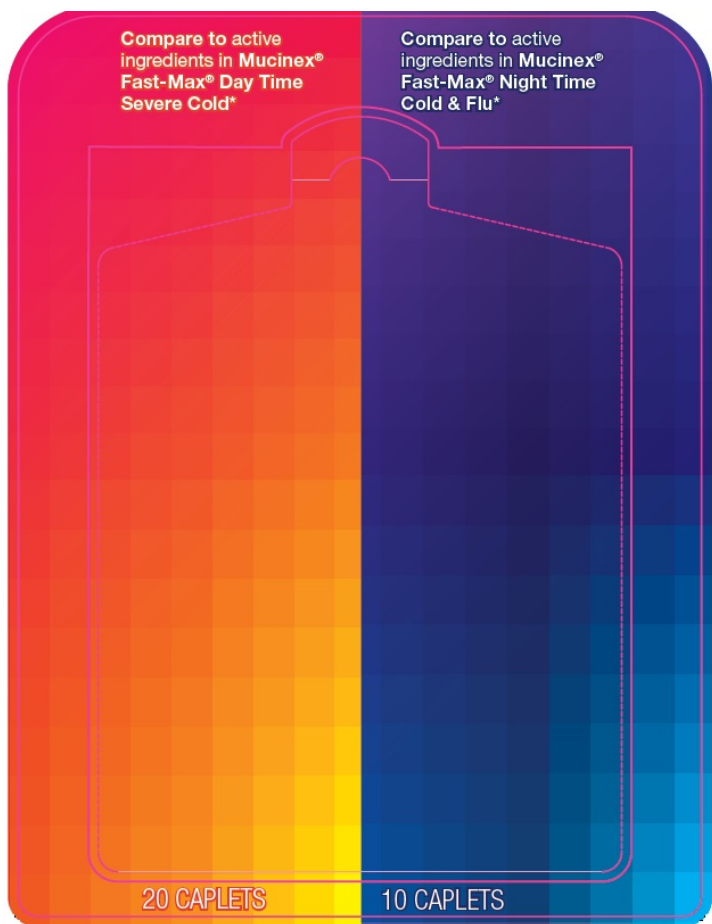
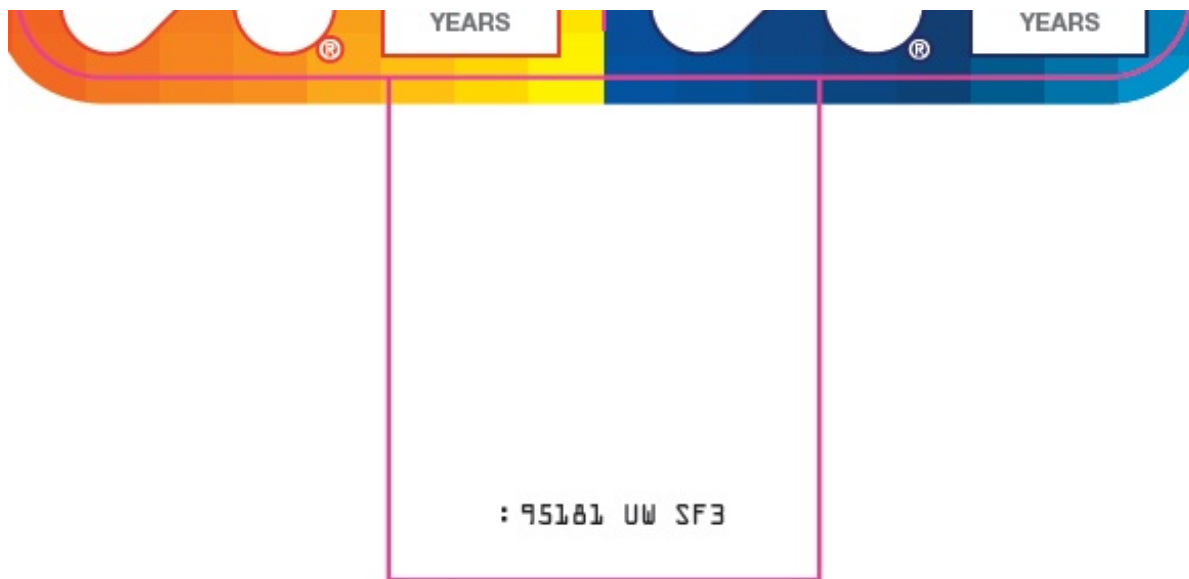


ACTUAL SIZE

AGES

**12+**

**up&up**



Dose every 4 hours.  
Do not take DAY TIME and NIGHT TIME caplets at the same time. Do not take more than a total of 10 caplets in a 24-hour period. Take only as directed.

**Drug Facts** **DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN**

**Active Ingredients**  
(In each caplet) **DAY TIME 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

**Purposes**

**Active Ingredients**  
(In each caplet) **NIGHT TIME Cold & Flu**  
Acetaminophen 325 mg.....Pain reliever/fever reducer  
Diphenhydramine HCl 25 mg.....Antihistamine  
Phenylephrine HCl 5 mg.....Nasal decongestant

**Purposes**

**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.



PEEL BACK HERE

**Drug Facts** (continued)

**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)

**Drug Facts** (continued)

■ 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

## UP AND UP DAYTIME SEVERE COLD NIGHTTIME COLD AND FLU

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

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11673-837
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### Packaging

#	Item Code	Package Description n	Marketing Start Date	Marketing End Date
1	NDC:11673-837-81	1 in 1 KIT; Type 0: Not a Combination Product	03/25/2015	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	10 BLISTER PACK	20
Part 2	5 BLISTER PACK	10

### Part 1 of 2

## UP AND UP DAYTIME SEVERE COLD

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated

### 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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

Color	RED	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	L922
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		10 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	03/16/2015	

### Part 2 of 2

#### UP AND UP NIGHTTIME COLD AND FLU

acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated

**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
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

**Inactive Ingredients**

Ingredient Name	Strength
CROSPVIDONE (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 DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	BLUE	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	16 mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**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
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**Labeler** - Target Corporation (006961700)

Revised: 12/2019

Target Corporation