# COLD FLU SEVERE DAY NIGHT- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride Harris Teeter

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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#### HTE - 1186 - 2019-1011

#### Cold + Flu Severe Day

#### **Drug Facts**

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever/fever
Acetaninophen 525 mg	reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- for the temporary relief of the following cold/flu symptoms:
  - minor aches and pain
  - headache
  - sore throat
  - nasal congestion
  - cough
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces fever

#### Warnings

#### Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. 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

- 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.
- if you have ever had an allergic reaction to this product or any of its 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
- 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 of pharmacist before use if you are

taking the blood thinning drug warfarin

#### When using this product

#### do not exceed recommended dosage

#### 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)

	<ul> <li>take 2 caplets every 4 hours</li> <li>swallow whole – do not crush, chew, or</li> </ul>
adults and children	<ul><li>dissolve</li><li>do not take more than 10 caplets in 24</li></ul>

	hours
children under 12	<ul> <li>ask a doctor</li> </ul>
years	

#### Other information

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information and warnings

#### **Inactive ingredients**

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #2 aluminum lake, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

#### Cold + Flu Severe Night Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever/fever
Acetaninophen 525 mg	reducer
Chlorpheniramine Maleate 2 mg	Antihistamine
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

#### Uses

- for the temporary relief of the following cold/flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion
  - cough
  - sinus congestion and pressure
  - sneezing and runny nose
- helps clear nasal passages
- relieves cough to help you sleep
- temporarily reduces fever

#### Warnings

#### Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. 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

- 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.
- if you have ever had an allergic reaction to this product or any of its 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
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

## Ask a doctor or pharmacist before use if you are

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

## When using this product

- do not exceed recommended dosage
- 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 vehicle or operating machinery

## 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 use more than directed (see overdose warning)

adults and children 12 years and over	<ul> <li>take 2 caplets every 4 hours</li> <li>swallow whole – do not crush, chew, or dissolve</li> <li>do not take more than 10 caplets in 24 hours</li> </ul>
children under 12 years	<ul> <li>ask a doctor</li> </ul>

#### Other information

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information and warnings

#### **Inactive ingredients**

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

## PRINCIPAL DISPLAY PANEL

Harris Teeter

Cold + Flu Severe

Day & Night

Compare to the Active Ingredients in Tylenol(R) Cold + Flu Severe Day and Night

For Adults

Day

Acetaminophen, Dextromethorphan HBr, Phenylephrine HCl, Guaifenesin

PAIN RELIEVER/FEVER REDUCER, COUGH SUPPRESSANT, NASAL DECONGESTANT, EXPECTORANT

Relief of

Head + Body Aches

Fever + Sore Throat

Cough, Nasal Congestion

Mucus & Chest Congestion

Night

Acetaminophen, Chlorpheniramine Maleate, Dextromethorphan HBr, Phenylephrine HCl

PAIN RELIEVER/FEVER REDUCER, ANTIHISTAMINE, COUGH SUPPRESSANT, NASAL DECONGESTANT

Relief of

Head + Body Aches

Fever + Sore Throat

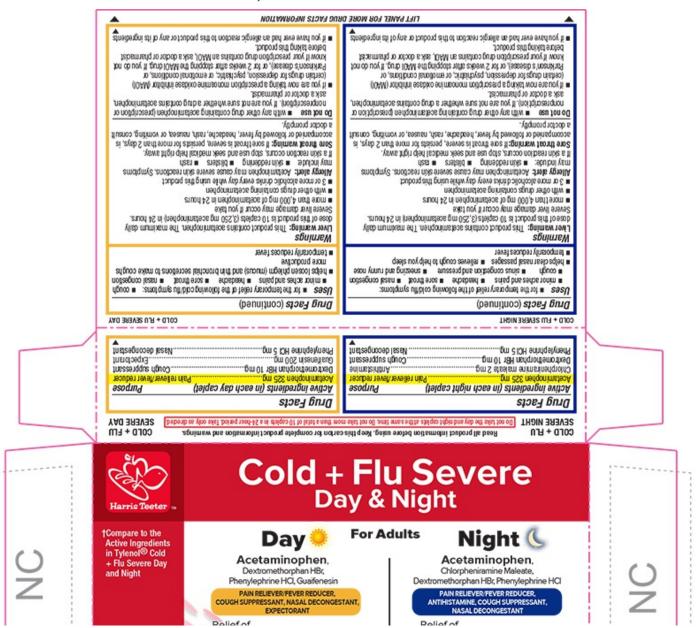
Cough

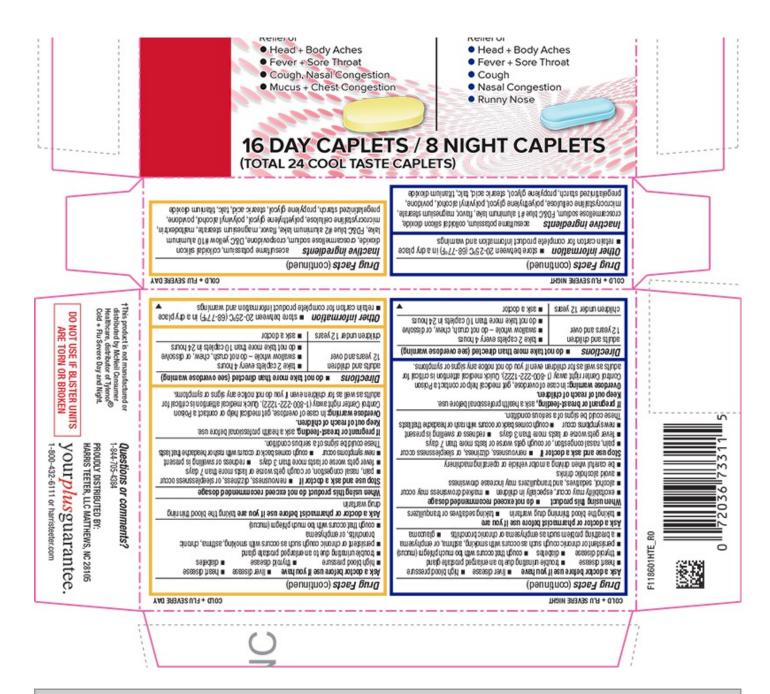
Nasal Congestion

Runny Nose

16 DAY CAPLETS / 8 NIGHT CAPLETS

(TOTAL 24 COOL TASTE CAPLETS)





## **COLD FLU SEVERE DAY NIGHT**

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride kit

Product Informat	ion				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72036-186		
Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:72036-186-01	1 in 1 CARTON	09/23/2019			
Quantity of Darts					
Quantity of Parts					
Part #	Package Quantity	Total Product (	Quantity		

## Part 1 of 2

## ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE, GUAIFENESIN, AND PHENYLEPHRINE HYDROCHLORIDE

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated

#### **Product Information**

Route of Administration

ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6 MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

macuve ingreatents	Inactive	Ingredients
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	Ingred	lient Name	Strengtl	h
ACESULFAME POTASSIUM (	UNII: 230V73Q5G9)			
SILICON DIO XIDE (UNII: ETJ7	Z6XBU4)			
CROSCARMELLOSE SODIUM	<b>4</b> (UNII: M280L1HH48)			
CROSPOVIDONE, UNSPECIFI	<b>ED</b> (UNII: 2S7830E561	1)		
D&C YELLOW NO. 10 (UNII: 3	35SW5USQ3G)			
ALUMINUM O XIDE (UNII: LMI	2606933)			
FD&C BLUE NO. 2 (UNII: L061	K8R7DQK)			
MAGNESIUM STEARATE (UN	II: 70097M6I30)			
MALTODEXTRIN (UNII: 7CVR	7L4A2D)			
CELLULOSE, MICROCRYSTA	ALLINE (UNII: OP1R32	D61U)		
POLYETHYLENE GLYCOL, U	UNSPECIFIED (UNII: 3)	WJQ0SDW1A)		
POLYVINYL ALCOHOL, UNS	PECIFIED (UNII: 532B	59J990)		
POVIDONE, UNSPECIFIED (U	,			
STARCH, PREGELATINIZED		/3SJ)		
PROPYLENE GLYCOL (UNII:	- /			
STEARIC ACID (UNII: 4ELV7Z6	65AP)			
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIO XIDE (UNII: 15F	FIX9 V2JP)			
<b>Product Characteristics</b>				
Color	yello w	Score	no score	

Shape					
	OVAL	Size		mm	
Flavor	MINT	Imprint Code	A	AA;1136	
Contains					
Packaging					
# Item Code	Package	Description N	larketing Start Dat	e Marketing	End Date
<b>1</b> 8 in 1 BL	ISTER PACK; Type	0: Not a Combination Product			
Marketing Infor	mation				
Marketing Category	Application Nu	mber or Monograph Citation	Marketing Start Dat	e Marketing	End Date
OTC monograph final	bart341				
Part 2 of 2					
Product Information					
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Route of Administration		L			
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Route of Administration	n ORA	L			
Route of Administration	n ORA		Basis of	Strength	Strengt
Route of Administration Active Ingredient/A	n ORA ctive Moiety Ingredien			U	Strengt 325 mg
Route of Administration Active Ingredient/A ACETAMINOPHEN (UNII: CHLORPHENIRAMINE M	n ORA Ctive Moiety Ingredien 36209ITL9D) (AC	t Name	ACETAMINOPH	U	325 mg
Route of Administration Active Ingredient/A ACETAMINOPHEN (UNII: CHLORPHENIRAMINE M UNII:3U6 IO 1965U) DEXTROMETHO RPHAN	n ORA Ctive Moiety Ingredien 36209ITL9D) (AC ALEATE (UNII: V14 HYDROBRO MIDE	<b>t Name</b> ETAMINOPHEN - UNII:36209ITL9D) Q0090J9Z) (CHLORPHENIRAMINE - E (UNII: 9D2RTI9KYH)	ACETAMINOPH	EN MINE MALEATE ORPHAN	325 mg
Route of Administration Active Ingredient/A ACETAMINOPHEN (UNII: CHLORPHENIRAMINE M UNII:3U6 IO 1965U) DEXTROMETHORPHAN (DEXTROMETHORPHAN - PHENYLEPHRINE HYDRO	n ORA Ctive Moiety Ingredien 36209ITL9D) (AC ALEATE (UNII: V14 HYDROBRO MIDE UNII:7355X3ROTS)	<b>t Name</b> ETAMINOPHEN - UNII:36209ITL9D) Q0090J9Z) (CHLORPHENIRAMINE - E (UNII: 9D2RTI9KYH)	ACETAMINOPH CHLORPHENIRA DEXTROMETHO	EN MINE MALEATE PRPHAN E E	325 mg 2 mg
Route of Administration Active Ingredient/A ACETAMINOPHEN (UNII: CHLORPHENIRAMINE M UNII:3U6 IO 1965U) DEXTROMETHORPHAN (DEXTROMETHORPHAN - PHENYLEPHRINE HYDRO	n ORA Ctive Moiety Ingredien 36209ITL9D) (AC ALEATE (UNII: V14 HYDROBRO MIDE UNII:7355X3ROTS)	<b>t Name</b> ETAMINOPHEN - UNII:36209ITL9D) Q009OJ9Z) (CHLORPHENIRAMINE - E (UNII: 9D2RTI9KYH) )	ACETAMINOPH CHLORPHENIRA DEXTROMETHO HYDROBROMID PHENYLEPHRIN	EN MINE MALEATE PRPHAN E E	325 mg 2 mg 10 mg
Route of Administration Active Ingredient/A ACETAMINOPHEN (UNII: CHLORPHENIRAMINE M UNII:3U6 IO 1965U) DEXTROMETHORPHAN - PHENYLEPHRINE HYDRO UNII:1WS297W6MV)	n ORA Ctive Moiety Ingredien 36209ITL9D) (AC ALEATE (UNII: V14 HYDROBRO MIDE UNII:7355X3ROTS) OCHLORIDE (UNII	<b>t Name</b> ETAMINOPHEN - UNII:36209ITL9D) Q009OJ9Z) (CHLORPHENIRAMINE - E (UNII: 9D2RTI9KYH) )	ACETAMINOPH CHLORPHENIRA DEXTROMETHO HYDROBROMID PHENYLEPHRIN	EN MINE MALEATE PRPHAN E E	325 mg 2 mg 10 mg
Route of Administration Active Ingredient/A ACETAMINOPHEN (UNII: CHLORPHENIRAMINE M UNII:3U6 IO 1965U) DEXTROMETHORPHAN - PHENYLEPHRINE HYDRO UNII:1WS 297W6 MV)	n ORA Ctive Moiety Ingredien 36209ITL9D) (AC ALEATE (UNII: V14 HYDROBRO MIDE UNII:7355X3ROTS) OCHLORIDE (UNII	<b>t Name</b> ETAMINOPHEN - UNII:36209ITL9D) Q009OJ9Z) (CHLORPHENIRAMINE - E (UNII: 9D2RTI9KYH) )	ACETAMINOPH CHLORPHENIRA DEXTROMETHO HYDROBROMID PHENYLEPHRIN	EN MINE MALEATE ORPHAN E E DE	325 mg 2 mg 10 mg
Route of Administration Active Ingredient/A ACETAMINOPHEN (UNII: CHLORPHENIRAMINE M UNII:3U6IO 1965U) DEXTROMETHORPHAN -	n ORA Ctive Moiety Ingredien 36209ITL9D) (AC ALEATE (UNII: V14 HYDROBRO MIDE UNII:7355X3ROTS) OCHLORIDE (UNII	t Name ETAMINOPHEN - UNII:362O9ITL9D) Q0O9OJ9Z) (CHLORPHENIRAMINE - E (UNII: 9D2RTI9KYH) ) E: 04JA59TNSJ) (PHENYLEPHRINE - Ingredient Name	ACETAMINOPH CHLORPHENIRA DEXTROMETHO HYDROBROMID PHENYLEPHRIN	EN MINE MALEATE ORPHAN E E DE	325 mg 2 mg 10 mg 5 mg

SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)

 FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

 ALUMINUM OXIDE (UNII: LMI26O6933)

 MAGNESIUM STEARATE (UNII: 70097M6I30)

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)

POLVETHYLENE GLYCOL, UNSPECIFIED (UNE 32320531990)       Image: State in the stat	MICRO CRYSTALLINE	CELLULOSE (UNII: OP1R3	32D61U)				
PV UBONE, UNSPECIFIED (UNII: F2989GF94E)       Image: Second Secon	POLYETHYLENE GLYC	POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)					
STARCH, PREGELATINIZED CORN (UNII: 08232N/35.)       Image: Constant of the stant	POLYVINYL ALCOHO	L, UNSPECIFIED (UNII: 53	2B59J990)				
PROPYLENE GLYCOL (UNI: 6DC90167V3)       Image: Starl CACID (UNI: 4ELV7265AP)       Image: Starl CACID (UNI: 4ELV7265AP)         TALC (UNI: 75EV7JARIU)       Image: Starl CACID (UNI: 4ELV7265AP)       Image: Starl CACID (UNI: 4ELV7265AP)         TTANUM DIO XIDE (UNI: 75EV7JARIU)       Image: Starl CACID (UNI: 4ELV7265AP)       Image: Starl CACID (UNI: 4ELV7265AP)         TTANUM DIO XIDE (UNI: 15FIX9V2JP)       Image: Starl CACID (UNI: 4ELV7265AP)       Image: Starl CACID (UNI: 4ELV7265AP)         Product Characteristics       Image: Starl CACID (UNI: 4ELV7265AP)       Image: Starl CACID (UNI: 4ELV7265AP)         Shape       V       Starl CACID (UNI: 4ELV7265AP)       Image: Starl CACID (UNI: 4ELV7265AP)         Shape       VAL       Starl CACID (UNI: 4ELV7265AP)       Image: Starl CACID (UNI: 4ELV7265AP)         Shape       VAL       Starl CACID (UNI: 4ELV7265AP)       Image: Starl CACID (UNI: 4ELV7265AP)         Shape       VAL       Starl CACID (UNI: 4ELV7265AP)       Image: Starl CACID (UNI: 4ELV726AP)         Shape       VAL       Starl CACID (UNI: 4ELV726AP)       Image: Starl CACID (UNI: 4ELV726AP)         Shape       VAL       Starl CACID (UNI: 4ELV726AP)       Marketing Starl CACID (UNI: 4ELV726AP)         Packaging       Application Number or Monograph Citation       Marketing Starl CACID (UNI: 4ELV726AP)	POVIDONE, UNSPECIFI	IED (UNII: FZ989GH94E)					
STEARIC ACID (UNII: 4ELV7265AP)   TALC (UNII: 7SEV7J4RIU)   TITANUM DIO XIDE (UNII: 15FIX3 V2JP)     Product Characteristics   Color blue   Score no score   Shape OVAL   Size 17mm   Flavor MINT   Ontains MINT      Packaging   # Item Code Package Description   Marketing Start Date Narketing End Date   Marketing Category Application Number or Monograph Citation   Marketing Start Date Marketing End Date	STARCH, PREGELATIN	IZED CORN (UNII: 08232	NY3SJ)				
TALC (UNIE: 75E V7J4R1U)       Image: Second	PROPYLENE GLYCOL	(UNII: 6DC9Q167V3)					
TITANIUM DIO XIDE (UNIE: 15FIX9 Y2JP)  Product Characteristics  Color blue Score noscore  Shape OVAL Size noscore  OVAL Size 17mm  Tamm  Flavor OVAL MINT Imprint Code AAA;139  Contains  Flavor OTA MINT Imprint Code  Package Description Marketing Start Date Marketing End Date  Packaging  I tem Code 8 in 1 BLISTER PACK; Type 0; Not a Combination Product  Marketing Category Application Number or Monograph Citation Marketing Start Date Application Start Date Marketing End Date  Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date  Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date  Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date  Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date  Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date  Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date	STEARIC ACID (UNII: 4E	ELV7Z65AP)					
Product Characteristics       no score         Color       blue       Score       no score         Shape       OVAL       Size       17mm         Flavor       MINT       Imprint Code       AAA;1139         Contains       Imprint Code       AAA;1139         Packaging       Imprint Code       Marketing Start Date         #       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       8 in 1 BLISTER PACK; Type 0; Not a Combination Product       Marketing Start Date       Marketing End Date         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing End Date         Marketing Information Product         Marketing Start Date       Marketing End Date         OTC monograph final       part34       Marketing Start Date       Marketing End Date         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing End Date	TALC (UNII: 7SEV7J4R1	U)					
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1       8 in 1 BLISTER PACK; Type 0: Not a Combination Product         1       8 in 1 BLISTER PACK; Type 0: Not a Combination Product         Marketing Information       Information         Marketing Category       Application Number or Monograph Citation         Marketing Start Date       Marketing End Date         OTC monograph final       part341         Marketing Information       Marketing Start Date         Marketing Category       Application Number or Monograph Citation         Marketing Start Date       Marketing End Date	Packaging						
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## Labeler - Harris Teeter (047279351)

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Harris Teeter