

**DAYTIME SEVERE COLD AND FLU NIGHTTIME SEVERE COLD, COUGH AND FLU-
acetaminophen, dextromethorphan hbr, phenylephrine hcl, diphenhydramine
hcl
H E B**

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.

**HEB Daytime Severe Cold & Flu, Nighttime Severe Cold, Cough & Flu Drug
Facts**

Active ingredients (in each packet) - Daytime

Acetaminophen 500 mg

Dextromethorphan HBr 20 mg

Phenylephrine HCl 10 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold:
- minor aches and pains
- minor sore throat pain
- headache
- nasal and sinus congestion
- cough due to minor throat and bronchial irritation
- temporarily reduces fever

Warnings

Liver warning: This product contains 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

- in a child under 12 years of age
- if you have ever had an allergic reaction to this product or any of its ingredients
- 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

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

Ask a doctor or 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 occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, cough or nasal congestion gets worse or lasts more than 7 days 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). Prompt 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)**
- take every 4 hours, while symptoms persist. Do not take more than 6 packets in 24 hours unless directed by a doctor.

Age	Dose
adults and children 12 years of age and over	one packet
children under 12 years of age	do not use

- dissolve contents of one packet into 8 oz. hot water: sip while hot. Consume entire drink within 10-15 minutes.
- if using a microwave, add contents of one packet to 8 oz. of cool water: stir briskly before and after heating. Do not overheat.

Other information

- **each packet contains:** potassium 10 mg and sodium 25 mg
- **phenylketonurics:** contains phenylalanine 22 mg per packet
- store at 20-25°C (68-77°F). Protect product from heat and moisture.

Inactive ingredients

acesulfame potassium, anhydrous citric acid, aspartame, colloidal silicon dioxide, D&C yellow #10, FD&C blue #1, FD&C red #40, flavors, maltodextrin, pregelatinized starch, sodium citrate, sucrose, tribasic calcium phosphate

Questions or comments?

1-800-719-9260

Active ingredients (in each packet) - Nighttime

Acetaminophen 650 mg

Diphenhydramine HCl 25 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Antihistamine/cough suppressant

Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold:
- minor aches and pains
- minor sore throat pain
- headache
- nasal and sinus congestion
- runny nose
- sneezing
- itchy nose or throat
- itchy, watery eyes due to hay fever
- cough due to minor throat and bronchial irritation
- temporarily reduces fever

Warnings

Liver warning: This product contains 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

- in a child under 12 years of age

- if you have ever had an allergic reaction to this product or any of its ingredients
- 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
- 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

- 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
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are

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

When using this product

- **do not exceed recommended dosage**
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- 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). Prompt 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)**
- take every 4 hours, while symptoms persist. Do not take more than 5 packets in 24 hours unless directed by a doctor.

Age	Dose
adults and children 12 years of age and over	one packet
children under 12 years of age	do not use

- dissolve contents of one packet into 8 oz. hot water: sip while hot. Consume entire drink within 10-15 minutes.
- if using a microwave, add contents of one packet to 8 oz. of cool water: stir briskly before and after heating. Do not overheat.

Other information

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- **phenylketonurics:** contains phenylalanine 13 mg per packet
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Inactive ingredients

acesulfame potassium, anhydrous citric acid, aspartame, colloidal silicon dioxide, D&C yellow #10, FD&C blue #1, FD&C red #40, flavors, maltodextrin, pregelatinized starch, sodium citrate, sucrose, tribasic calcium phosphate

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to Theraflu® Multi-Symptom Severe Cold active ingredients

H•E•B

DAYTIME

Severe Cold & Flu

Acetaminophen / Pain Reliever/Fever Reducer

Dextromethorphan HBr / Cough Suppressant

Phenylephrine HCl / Nasal Decongestant

Multi-Symptom

Relief of:

- Pain
- Fever
- Cough
- Nasal Congestion

Green Tea & Honey Lemon Flavors

6 PACKETS

Compare to Theraflu® Nighttime Severe Cold & Cough active ingredients

H•E•B

NIGHTTIME

Severe Cold, Cough & Flu

Acetaminophen / Pain Reliever/Fever Reducer

Diphenhydramine HCl / Antihistamine / Cough Suppressant

Phenylephrine HCl / Nasal Decongestant

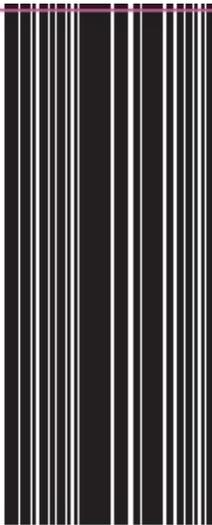
Multi-Symptom

Relief of:

- Pain
- Fever
- Cough
- Nasal Congestion
- Sneezing

Honey Lemon Infused with White Tea Flavors

6 PACKETS



Compare to *Theraflu® Multi-Symptom Severe Cold* active ingredients*

Compare to *Theraflu® Nighttime Severe Cold & Cough* active ingredients*

NDC 37808-602-55



DAYTIME Severe Cold & Flu

Acetaminophen / Pain Reliever/Fever Reducer
Dextromethorphan HBr / Cough Suppressant
Phenylephrine HCl / Nasal Decongestant

Multi-Symptom

Relief of:

- Pain
- Fever
- Cough
- Nasal Congestion

Green Tea & Honey Lemon Flavors



6 PACKETS



NIGHTTIME Severe Cold, Cough & Flu

Acetaminophen / Pain Reliever/Fever Reducer
Diphenhydramine HCl / Antihistamine / Cough Suppressant
Phenylephrine HCl / Nasal Decongestant

Multi-Symptom

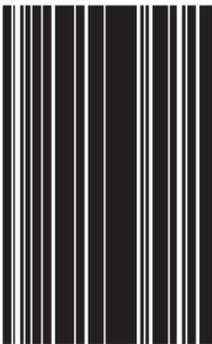
Relief of:

- Pain
- Fever
- Cough
- Nasal Congestion
- Sneezing

Honey Lemon Infused with White Tea Flavors



6 PACKETS



DO NOT TAKE BOTH PRODUCTS AT THE SAME TIME OR TAKE MORE THAN 5 DOSES IN TOTAL IN ANY 24 HOUR PERIOD.

DO NOT TAKE A DOSE OF THE NIGHTTIME PRODUCT SOONER THAN 4 HOURS AFTER THE LAST DOSE OF MULTI-SYMPTOM PRODUCT UNLESS DIRECTED BY YOUR DOCTOR.

Daytime Flu & Severe Cold

Drug Facts

Active ingredients (in each packet)	Purposes
Acetaminophen 500 mg.....	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg.....	Cough suppressant
Phenylephrine HCl 10 mg.....	Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold:
 - minor aches and pains
 - minor sore throat pain
 - headache
 - nasal and sinus congestion
 - cough due to minor throat and bronchial irritation
 - temporarily reduces fever

Warnings

Liver warning: This product contains 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

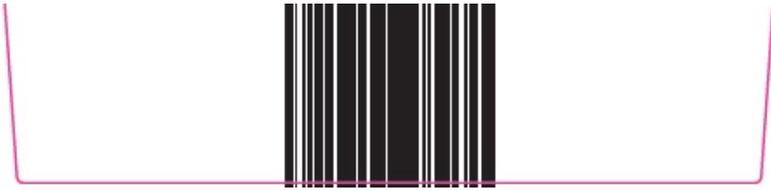
- in a child under 12 years of age
- if you have ever had an allergic reaction to this product or any of its ingredients
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are 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

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

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

When using this product do not exceed recommended dosage



Multi-Symptom

Acetaminophen / Pain Reliever/Fever Reducer
Diphenhydramine HCl / Antihistamine / Cough Suppressant
Phenylephrine HCl / Nasal Decongestant

Severe Cold, Cough & Flu

NIGHTTIME

H-E-B

Multi-Symptom

Acetaminophen / Pain Reliever/Fever Reducer
Dextromethorphan HBr / Cough Suppressant
Phenylephrine HCl / Nasal Decongestant

Severe Cold & Flu

DAYTIME

H-E-B

Drug Facts (continued)

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- 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). Prompt 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)
- take every 4 hours, while symptoms persist. Do not take more than 6 packets in 24 hours unless directed by a doctor.

Drug Facts (continued)

Age	Dose
adults and children 12 years of age and over	one packet
children under 12 years of age	do not use

- dissolve contents of one packet into 8 oz. hot water: sip while hot. Consume entire drink within 10-15 minutes.
- if using a microwave, add contents of one packet to 8 oz. of cool water; stir briskly before and after heating. Do not overheat.

Other information

- each packet contains: potassium 10 mg and sodium 25 mg
- phenylketonurics: contains phenylalanine 22 mg per packet
- store at 20-25°C (68-77°F). Protect product from heat and moisture.

Inactive ingredients aceulfame potassium, anhydrous citric acid, aspartame, colloidal silicon dioxide, D&C yellow #10, FD&C blue #1, FD&C red #40, flavors, maltodextrin, pregelatinized starch, sodium citrate, sucrose, tribasic calcium phosphate

Questions or comments? 1-800-719-9260

Nighttime Severe Cold & Cough

Drug Facts

Active ingredients (in each packet)

Acetaminophen 650 mg.....Pain reliever/fever reducer
Diphenhydramine HCl 25 mg.....Antihistamine/cough suppressant
Phenylephrine HCl 10 mg.....Nasal decongestant

Purposes

- Uses**
- temporarily relieves these symptoms due to a cold:
 - minor aches and pains
 - minor sore throat pain
 - nasal and sinus congestion
 - headache
 - itchy nose or throat
 - runny nose
 - sneezing
 - itchy, watery eyes due to hay fever
 - cough due to minor throat and bronchial irritation
 - temporarily reduces fever

Warnings

Liver warning: This product contains 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.

Drug Facts (continued)

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 ■ in a child under 12 years of age ■ if you have ever had an allergic reaction to this product or any of its ingredients

■ 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

■ 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

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

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are

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

When using this product ■ do not exceed recommended dosage

- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- 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). Prompt 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)
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Inactive ingredients aceulfame potassium, anhydrous citric acid, aspartame, colloidal silicon dioxide, D&C yellow #10, FD&C blue #1, FD&C red #40, flavors, maltodextrin, pregelatinized starch, sodium citrate, sucrose, tribasic calcium phosphate

Questions or comments? 1-800-719-9260

*These products are not manufactured or distributed by GSK Consumer Healthcare, distributor of Theraflu® Multi-Symptom Severe Cold and Theraflu® Nighttime Severe Cold & Cough.

Do not use if printed packets are torn or punctured

GLUTEN FREE

100% GUARANTEE

premise

MADE IN MEXICO
MADE WITH
PRIDE & CARE FOR H-E-B®
SAN ANTONIO, TX 78204

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

H-E-B

If you aren't completely pleased with this product, we'll be happy to replace it or refund your money. You have our word on it.

10033-1808



1E055 1J C1

DAYTIME SEVERE COLD AND FLU NIGHTTIME SEVERE COLD, COUGH AND FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl, diphenhydramine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-602
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-602-55	1 in 1 CARTON; Type 0: Not a Combination Product	12/10/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 CARTON	6
Part 2	1 CARTON	6

Part 1 of 2

SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl powder, for solution

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	HONEY (green tea) , LEMON (green tea)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		6 in 1 CARTON; 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	12/10/2018	

Part 2 of 2

SEVERE COLD, FLU AND COUGH

acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride powder, for solution

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics

Color	WHITE (mixture of white, light yellow-orange particles) , ORANGE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		6 in 1 CARTON; 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	12/10/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/10/2018	

