CEDAPRIN- ibuprofen tablet
Honeywell Safety Products USA, Inc

0498-7500, 0498-7501 & 0498-7502: Cedaprin

Active Ingredient (in each tablet)

Ibuprofen 200 mg (NSAID)

*(nonsteroidal anti-inflammatory drug)

Purpose

Pain reliever/fever reducer

Uses

temporarily relieves minor aches and pains due to:

- headache
- muscular aches
- minor pain of arthritis
- toothache
- backache
- the common cold
- menstrual cramps

- temporarily reduces fever

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems

- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning:
- NSAID's, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use
- if you have ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if
- you have problems or serious side effectsfrom taking pain relievers or fever reducers
- stomach bleeding warning applies to you
- you have a history of stomach problems such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma or had a stroke
- you are taking a diuretic

Ask a doctor or a pharmacist before use if you are
- taking aspirin for heart attack or stroke, because ibuprofen may decrease the benefit of aspirin
- under a doctors care for any serious condition
- taking any other drug

When using this product,

take with food or milk if stomach upset occurs

Stop use and ask a doctor if
- you experience any of the following signs of stomach bleeding:
- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better

- you have symptoms of heart problems or stroke:
- chest pain
- trouble breathing
- weakness in oe part or side of body
- slurred speech
- leg swelling

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days

- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

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 take more than directed**
- **the smallest effective dose should be used**
- adult and children 12 years of age and over:
- take 1 tablet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 tablet, 2 tablets may be used
- do not exceed 6 tablets in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

Other Information

- store between 15 ^{o}-30 ^{o}C (59 ^{o}-86 ^{o}F)
- avoid excessive heat and humidity
- TAMPER EVIDENT PACKETS- DO NOT USE IF OPEN OR TORN

Inactive ingredients

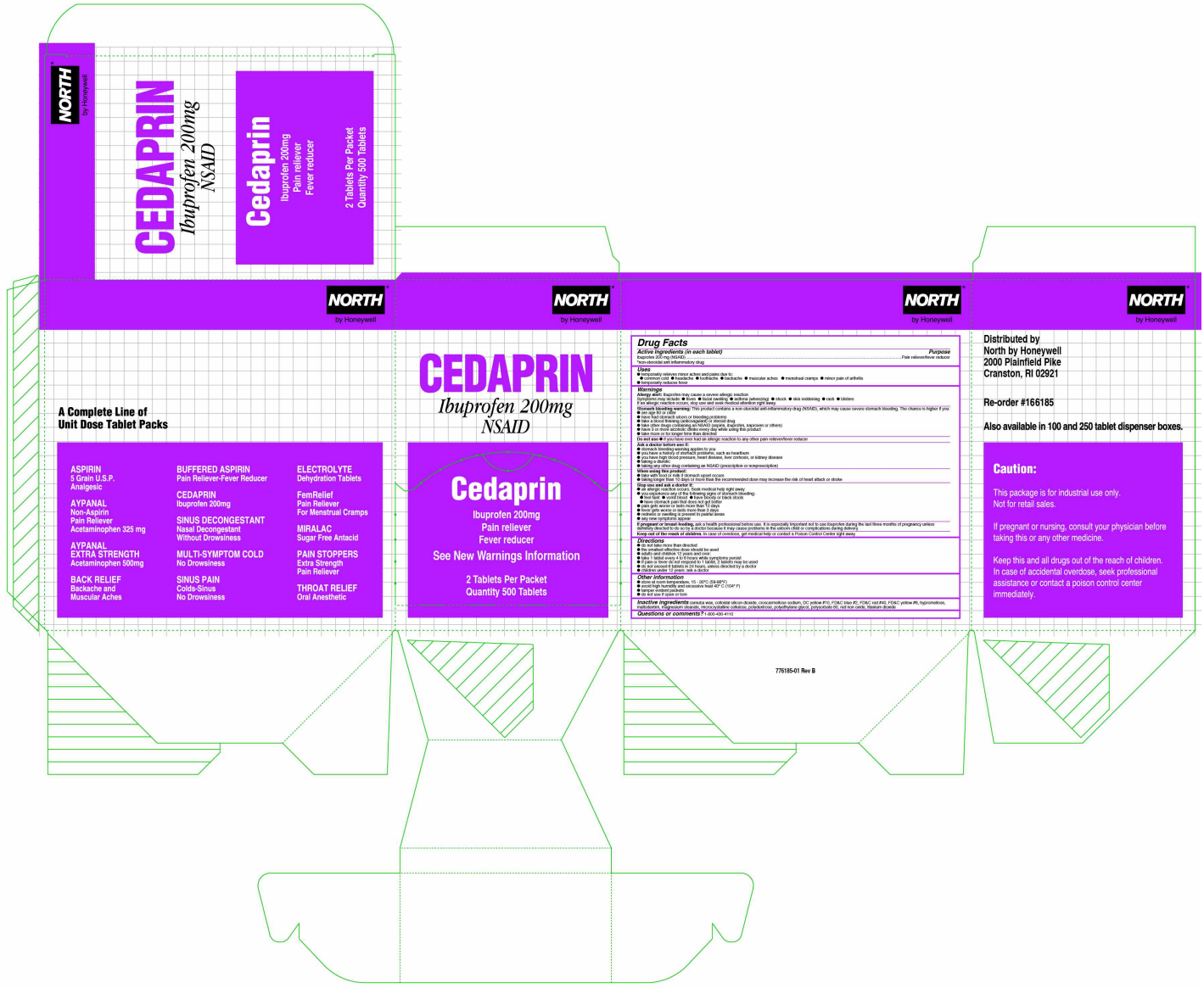
hypromellose, lactose monohydrate, opadry II 31K, povidone K-30, ferric oxide red, silicon dioxide, starch, stearic acid, titanium dioxide, triacetin

Questions or comments?

1-800-430-5490

Cedaprin Old

MM1



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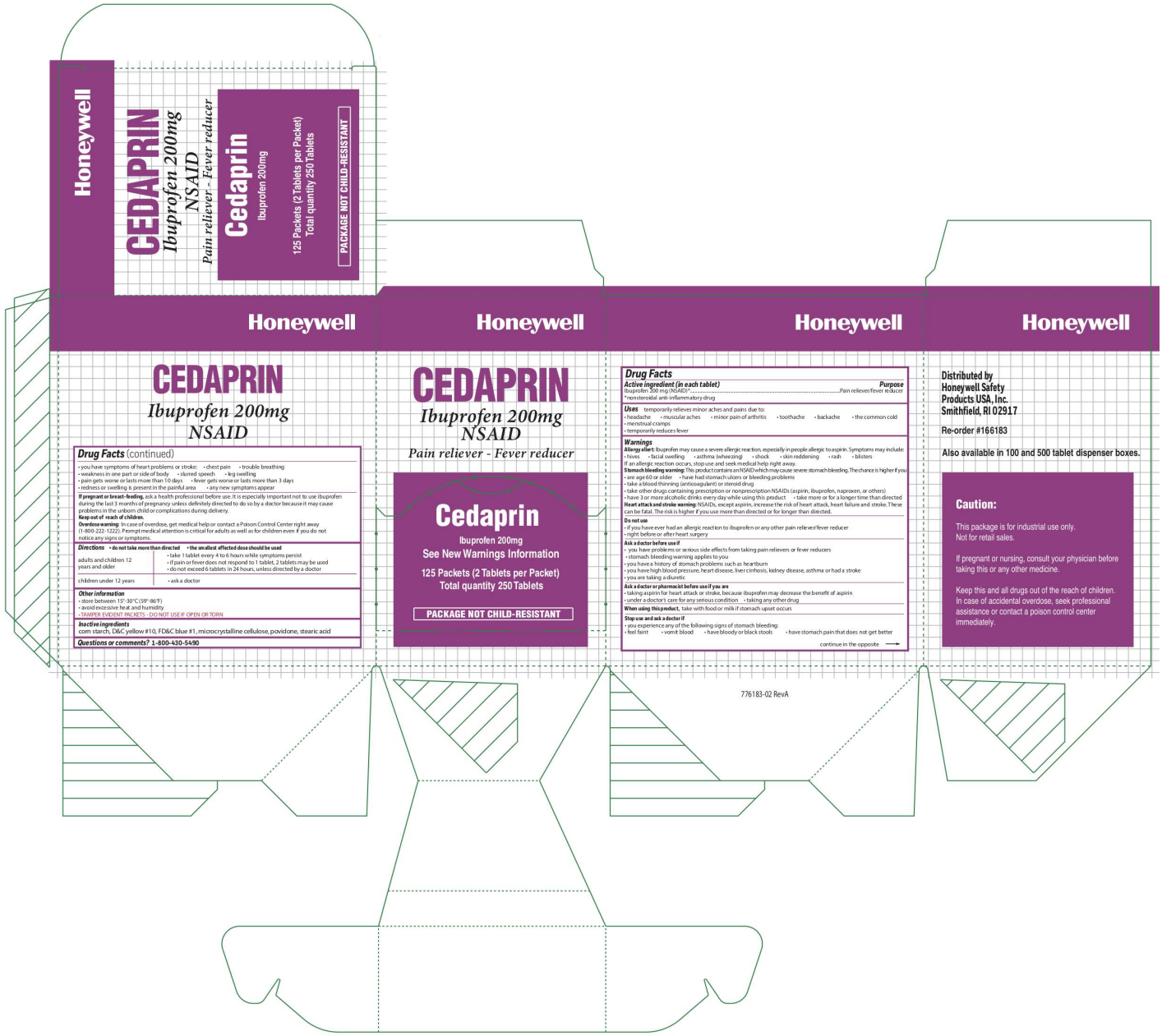
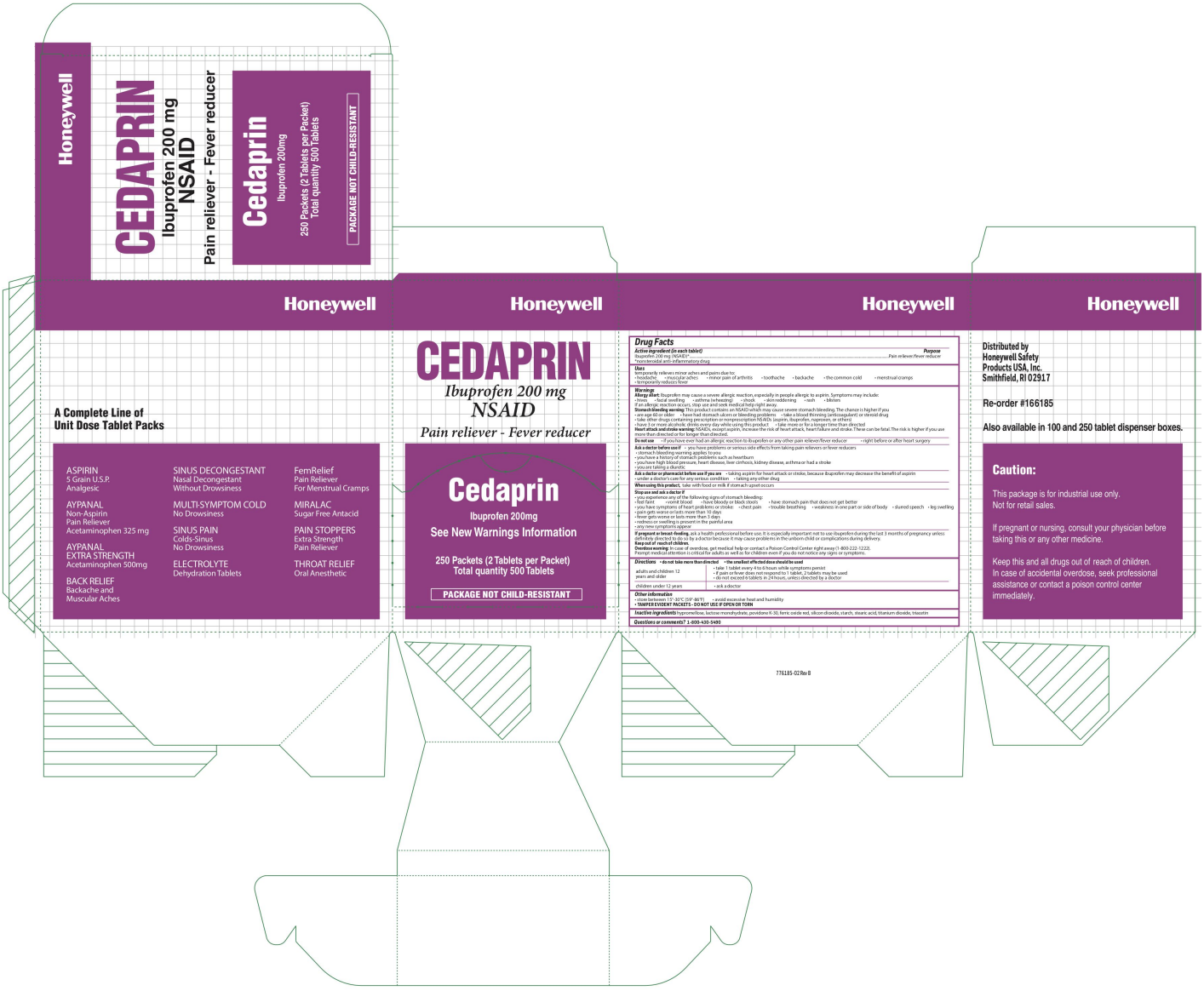
Cedaprin



Cedeprin 7502



CEDAPRIN

ibuprofen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-7502
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
TRIACETIN (UNII: XHX3C3X673)	
STARCH, CORN (UNII: O8232NY3SJ)	

POVIDONE K30 (UNII: U725QWY32X)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Product Characteristics

Color	red	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	G;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-7502-10	100 in 1 BOX	01/02/2017	
1	NDC:0498-7502-01	2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0498-7502-25	250 in 1 BOX	07/23/2019	
2	NDC:0498-7502-01	2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:0498-7502-50	500 in 1 BOX	01/02/2017	
3	NDC:0498-7502-01	2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079129	01/02/2017	

CEDAPRIN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-7500
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYETHYLENE GLYCOL (UNII: 3WQ0SDW1A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	brown (CHOCOLATE BROWN)	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	IBU;200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-7500-50	250 in 1 BOX	03/07/2012	01/01/2017
1	NDC:0498-7500-25	125 in 1 BOX		
1	NDC:0498-7500-10	50 in 1 BOX		
1	NDC:0498-7500-01	2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079129	03/07/2012	01/01/2017

CEDAPRIN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-7501
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYETHYLENE GLYCOL (UNII: 3WQ0SDW1A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	brown (CHOCOLATE BROWN)	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	IBU;200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-7501-10	100 in 1 BOX	01/02/2017	
1	NDC:0498-7501-01	2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0498-7501-25	250 in 1 BOX	01/02/2017	
2	NDC:0498-7501-01	2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:0498-7501-50	500 in 1 BOX	01/02/2017	
3	NDC:0498-7501-01	2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079129	01/02/2017	

Labeler - Honeywell Safety Products USA, Inc (118768815)

Registrant - Honeywell Safety Products USA, Inc (118768815)

Revised: 1/2024 Honeywell Safety Products USA, Inc