NAPROXEN SODIUM- naproxen sodium tablet
HARMON STORES INC.

Naproxen Sodium Tablets, USP 220 mg (NSAID)**
Pain reliever/fever reducer
Strength to last 12 HOURS

Active ingredient (For Tablet)

(in each tablet)

Naproxen sodium 220 mg

(naproxen 200 mg) (NSAID)**

**nonsteroidal anti-inflammatory drug

Active ingredient (For Caplet)

(in each caplet)

Naproxen sodium 220 mg

(naproxen 200 mg) (NSAID)**

**nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

■ temporarily relieves minor aches and pains due to:

■ minor pain of arthritis

■ muscular aches

■ backache

■ menstrual cramps

■ headache

■ toothache

■ the common cold

■ temporarily reduces fever

Allergy alert:

Naproxen sodium 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:

NSAIDs, 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 any other pain reliever/fever reducer

■ right before or after heart surgery

Ask a doctor before use if

■ the 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

■ you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

■ under a doctor’s 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 one 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

■ you have difficulty swallowing

■ it feels like the pill is stuck in your throat

■ 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 naproxen sodium 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 the reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions (For Tablets)

■ **do not take more than directed**

■ **the smallest effective dose should be used**

■ drink a full glass of water with each dose

Adults and children 12 years and older

■ take 1 tablet every 8 to 12 hours while symptoms last

■ for the first dose you may take 2 tablets within the first hour

■ do not exceed 2 tablets in any 8- to 12- hour period

■ do not exceed 3 tablets in a 24- hour period

Children under 12 years

■ ask a doctor

Directions (For Caplets)

■ **do not take more than directed**

■ **the smallest effective dose should be used**

■ drink a full glass of water with each dose

Adults and children 12 years and older

■ take 1 caplet every 8 to 12 hours while symptoms last

■ for the first dose you may take 2 caplets within the first hour

■ do not exceed 2 caplets in any 8- to 12- hour period

■ do not exceed 3 caplets in a 24- hour period

Children under 12 years

■ ask a doctor

Other information (For Tablet)

■ **each tablet contains:** sodium 20 mg

■ store at 20 - 25°C (68 - 77°F). Avoid high humidity and excessive heat above 40°C (104°F)

Other information (For Caplet)

■ **each caplet contains:** sodium 20 mg

■ store at 20 - 25°C (68 - 77°F). Avoid high humidity and excessive heat above 40°C (104°F)

Inactive ingredients

FD&C blue #2 aluminum lake, hypromellose, maize starch, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, titanium dioxide.

Questions or comments?

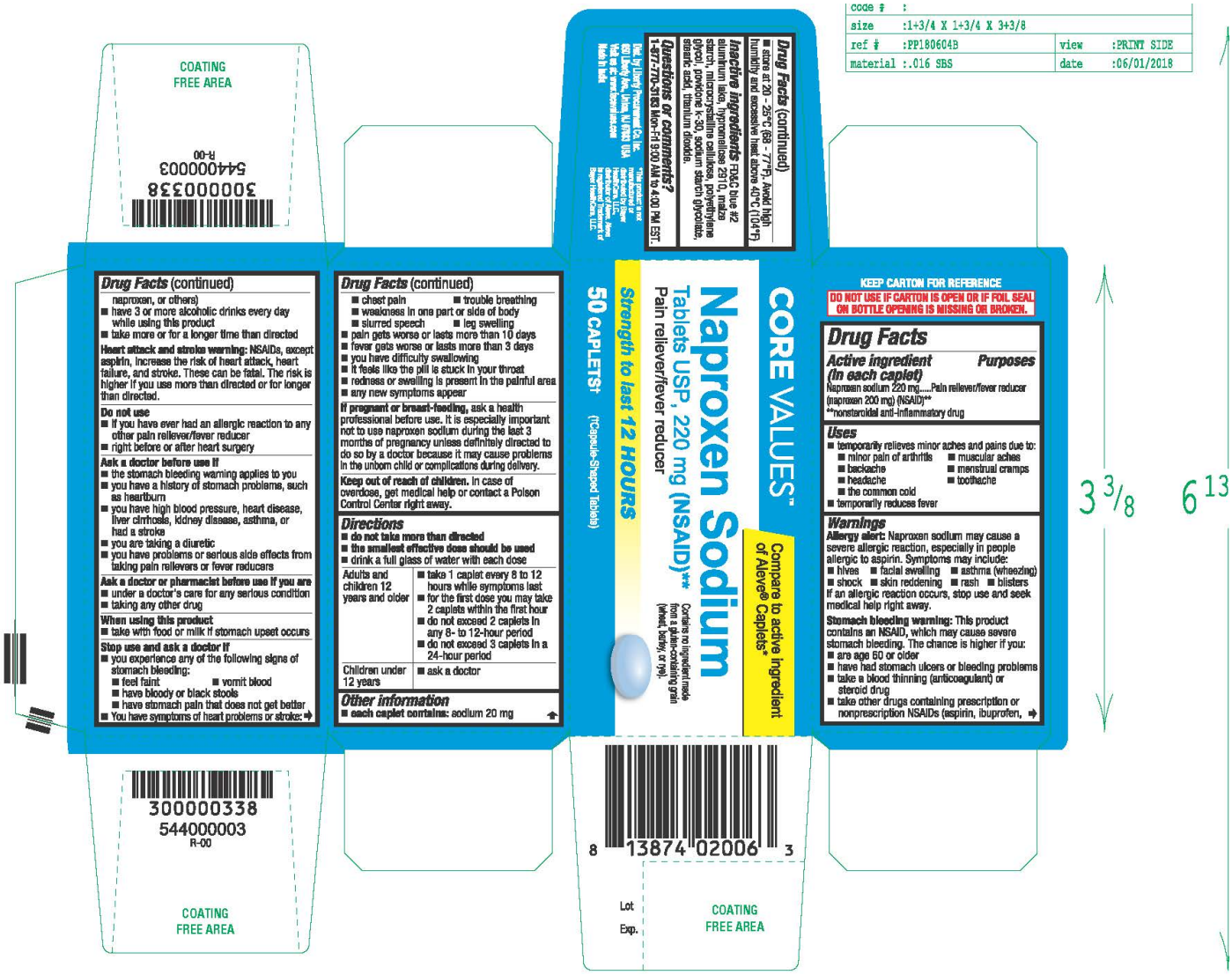
1-877-770-3183 Mon - Fri 9:00 AM to 4:00 PM EST.

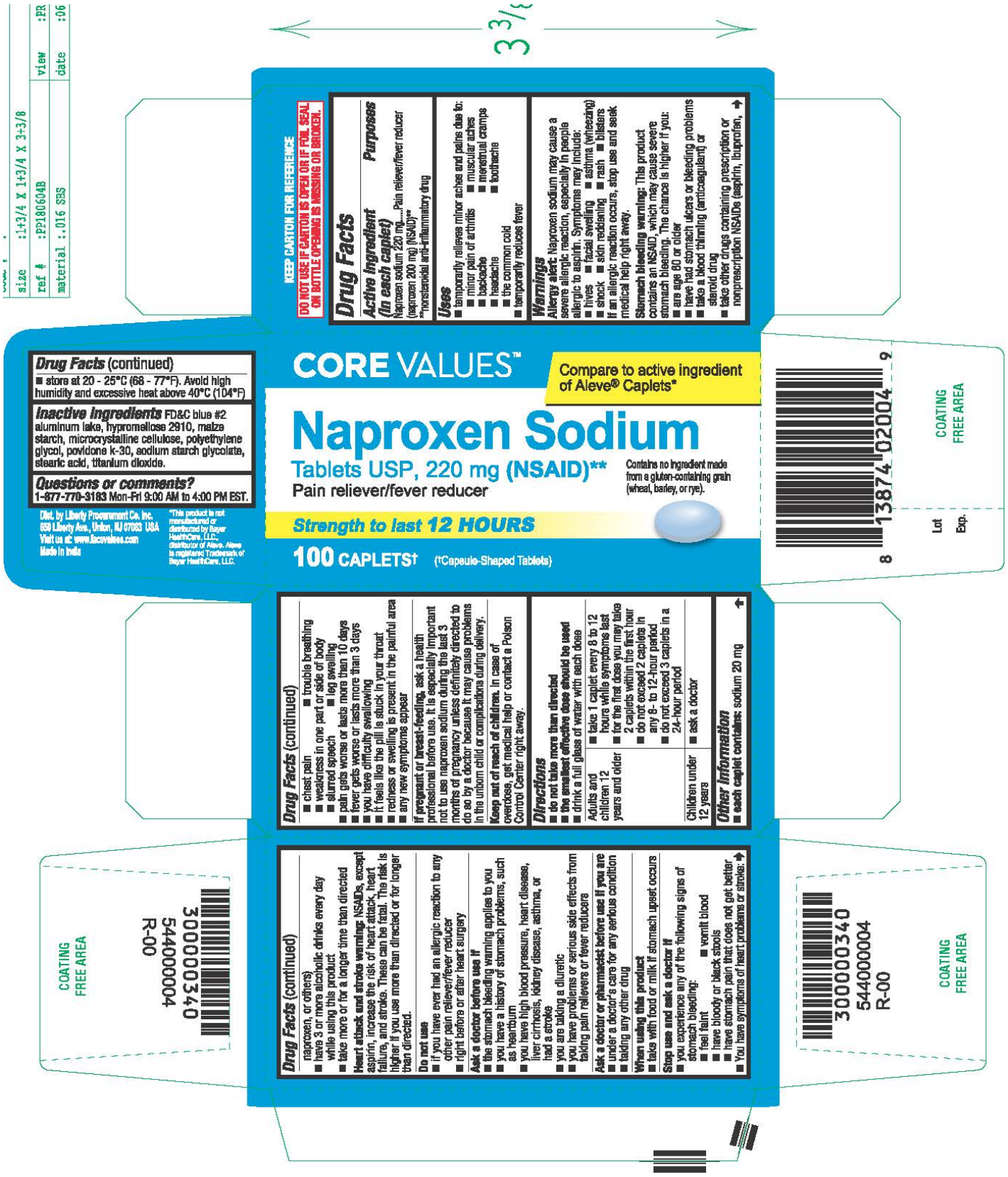
Tablets

size :1+3/4 X 1+3/4 X 3+3/8
ref # :PP1806G4B
material :.016 SBS
view :PRINT SI
date :06/01/20
3 3/8
KEEP CARTON FOR REFERENCE
DO NOT USE IF CARTON IS OPEN OR IF FOIL SEAL ON BOTTLE OPENING IS MISSING OR BROKEN.
Drug Facts
Active Ingredient (In each tablet)
Purposes
Naproxen sodium 220 mg.....Pain reliever/fever reducer
(naproxen 200 mg) (NSAID)**
**nonsteroidal anti-inflammatory drug
Uses
■ temporarily relieves minor aches and pains due to:
■ minor pain of arthritis
■ backache
■ headache
■ the common cold
■ muscular aches
■ menstrual cramps
■ toothache
■ temporarily reduces fever
Warnings
Allergy alert: Naproxen sodium 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 warnings: 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,
CORE VALUES™
Compare to active ingredient of Aleve® Tablets*
Naproxen Sodium
Tablets USP, 220 mg (NSAID)**
Pain reliever/fever reducer
Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye).
Strength to last 12 HOURS
50 TABLETS
Drug Facts (continued)
■ store at 20 - 25°C (68 - 77°F). Avoid high humidity and excessive heat above 40°C (104°F)
Inactive ingredients FD&C blue #2 aluminum lake, hypromellose 2910, maize starch, microcrystalline cellulose, polyethylene glycol, povidone k-30, sodium starch glycolate, stearic acid, titanium dioxide.
Questions or comments?
1-877-770-3183 Mon-Fri 9:00 AM to 4:00 PM EST.
Dist. by Liberty Procurement Co. Inc.
650 Liberty Ave., Union, NJ 07083 USA
Visit us at: www.facevalues.com
Made in India
*This product is not manufactured or distributed by Bayer HealthCare, LLC., distributor of Aleve. Aleve is registered Trademark of Bayer HealthCare, LLC.
8 13874 02008 7
Lot
Exp.
COATING FREE AREA
Drug Facts (continued)
■ chest pain ■ trouble breathing
■ weakness in one 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
■ you have difficulty swallowing
■ it feels like the pill is stuck in your throat
■ 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 naproxen sodium 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. In case of overdose, get medical help or contact a Poison Control Center right away.
Directions
■ do not take more than directed
■ the smallest effective dose should be used
■ drink a full glass of water with each dose
Adults and children 12 years and older
■ take 1 tablet every 8 to 12 hours while symptoms last
■ for the first dose you may take 2 tablets within the first hour
■ do not exceed 2 tablets in any 8- to 12-hour period
■ do not exceed 3 tablets in a 24-hour period
Children under 12 years
■ ask a doctor
Other Information
■ each tablet contains: sodium 20 mg
Drug Facts (continued)
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 warnings: NSAIDs, 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 any other pain reliever/fever reducer
■ right before or after heart surgery
Ask a doctor before use if
■ the 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
■ you have problems or serious side effects from taking pain relievers or fever reducers
Ask a doctor or pharmacist before use if you are
■ under a doctor's 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:
COATING FREE AREA
300000342
544000005
R-00
300000342
544000005
R-00
COATING FREE AREA

Caplets

code #	:		
size	:1+3/4 X 1+3/4 X 3+3/8		
ref #	:PP180604B	view	:PRINT SIDE
material	:.016 SBS	date	:06/01/2018





NAPROXEN SODIUM

naproxen sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63940-761

Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	blue	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	220
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63940-761-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	10/01/2018	

NAPROXEN SODIUM

naproxen sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63940-763
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	blue	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	220
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63940-763-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	
2	NDC:63940-763-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	10/01/2018	

Labeler - HARMON STORES INC. (804085293)

Revised: 12/2019 HARMON STORES INC.