PROXEN NP 660- naproxen sodium tablet
OPMX LLC

PROXEN NP 660

Drug Facts

Active ingredient (in each tablet) Purposes

Naproxen sodium 220 mg (naproxen 200mg) (NSAID)* .....Pain reliever/fever reducer

*nonsteroidal anti-inflammatory drug

Uses

■ temporarily relieves minor aches and pains due to:

■ headache ■ backache ■ muscular aches

■ the common cold ■ toothache ■ menstrual cramps

■ minor pain of arthritis ■ temporarily reduces fever

Warnings

Allergy alert:

Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

■ hives ■ asthma (wheezing) ■ skin reddening

■ facial swelling ■ shock ■ 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

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, or kidney disease

■ you are taking a diuretic

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

■ you have asthma

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

■ the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

■ side effects occur.

You may report side effects to FDA at 1-800-FDA-1088.

■ 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

■ 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 to12 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

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

■ read all product information before using

■ **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, FD&C Blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide

Questions or comments?

Call: (619) 600-5632 (Mon-Fri 9AM – 5PM EST) or https://www.opmx.us

PRINCIPAL DISPLAY PANEL 12 CAPLETS

NDC 69729-123-12

PROXEN NP 660

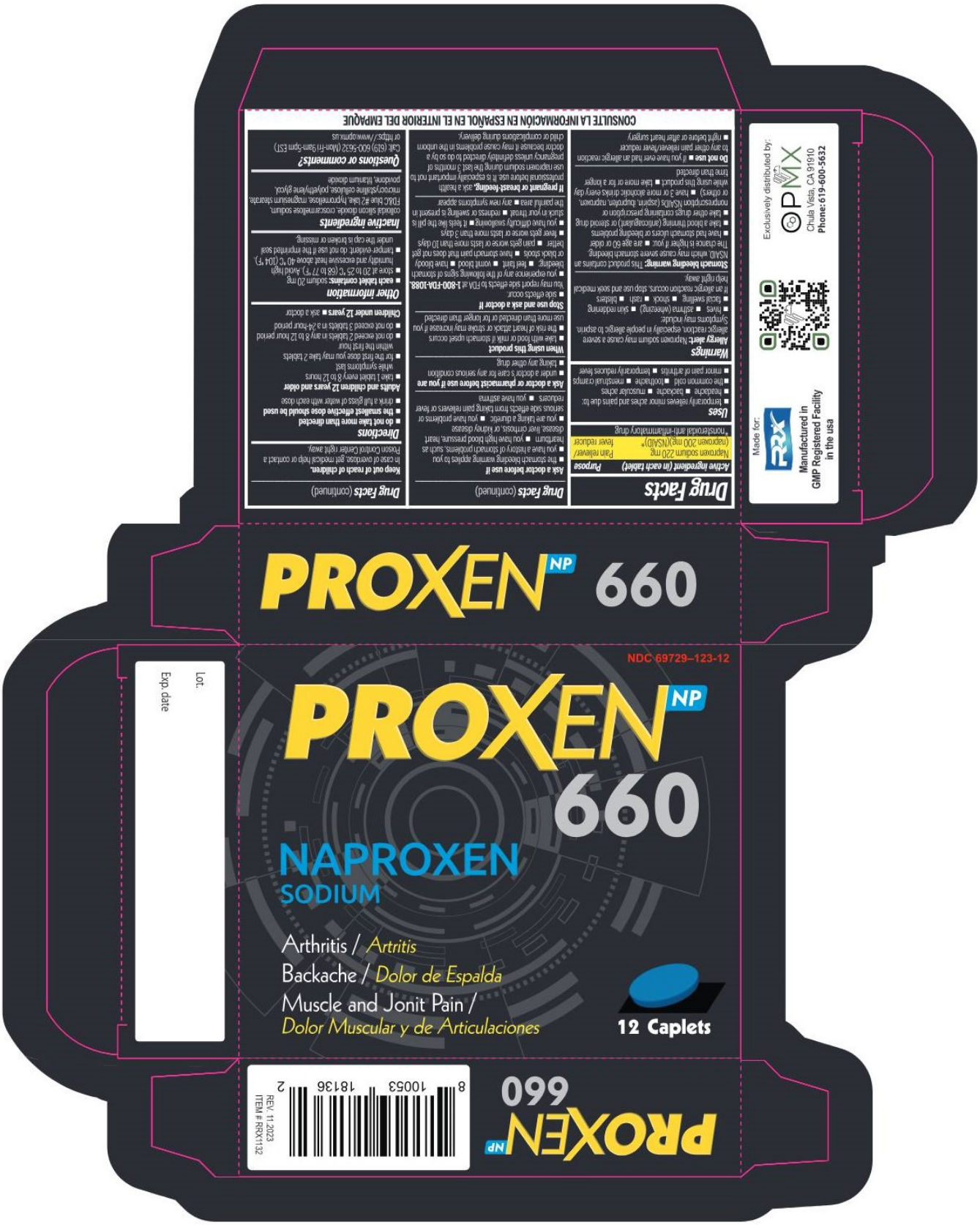
NAPROXEN SODIUM

Arthritis/Artritis

Backache/Dolor de Espalda

Muscle and Joint Pain/ Dolor Muscular y de Articulaciones

12 Caplets



PRINCIPAL DISPLAY PANEL 24 CAPLETS

NDC 69729-123-24

PROXEN NP 660

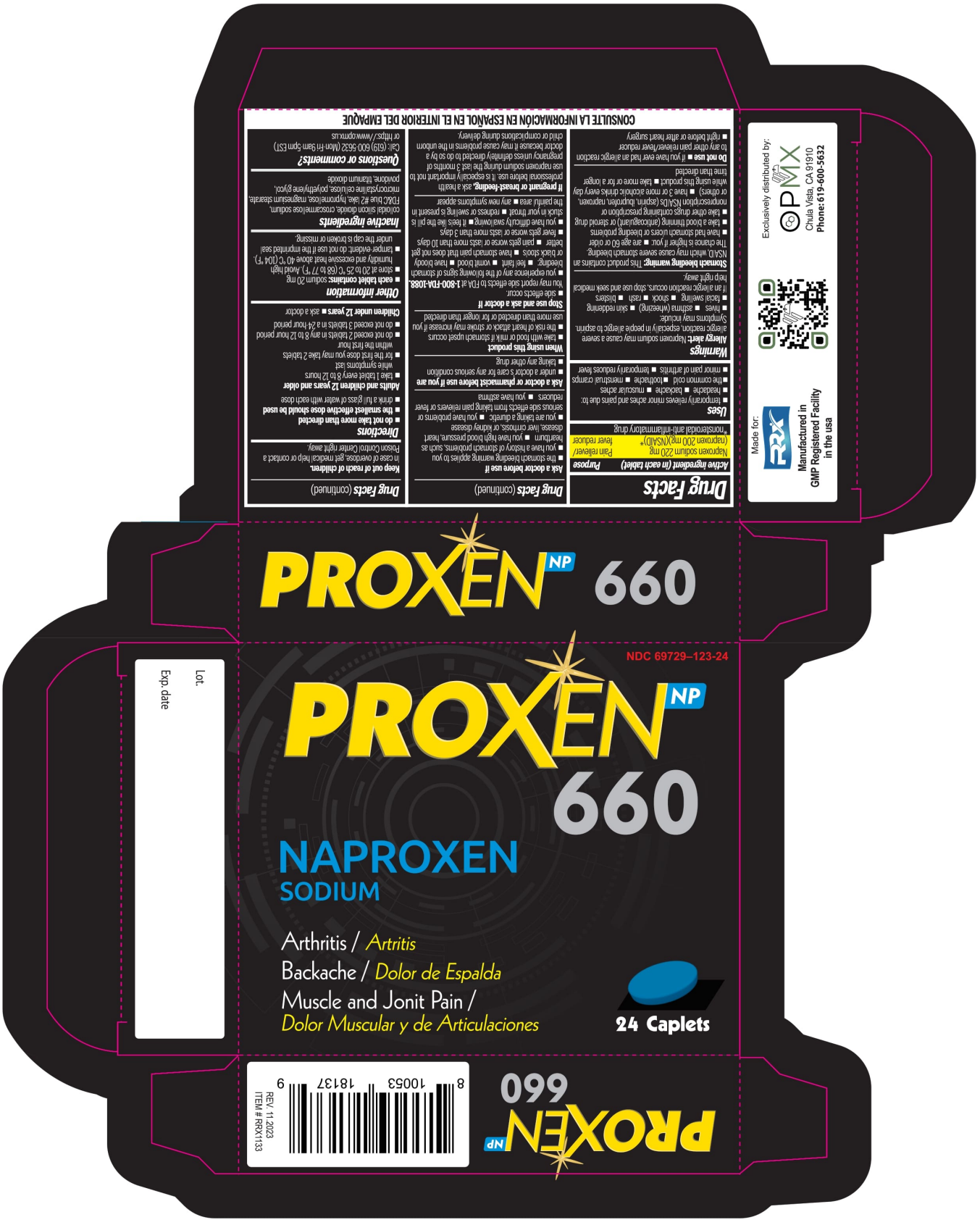
NAPROXEN SODIUM

Arthritis/Artritis

Backache/Dolor de Espalda

Muscle and Joint Pain/ Dolor Muscular y de Articulaciones

24 Caplets



PRINCIPAL DISPLAY PANEL 100 CAPLETS

NDC 69729-123-50

PROXEN NP 660

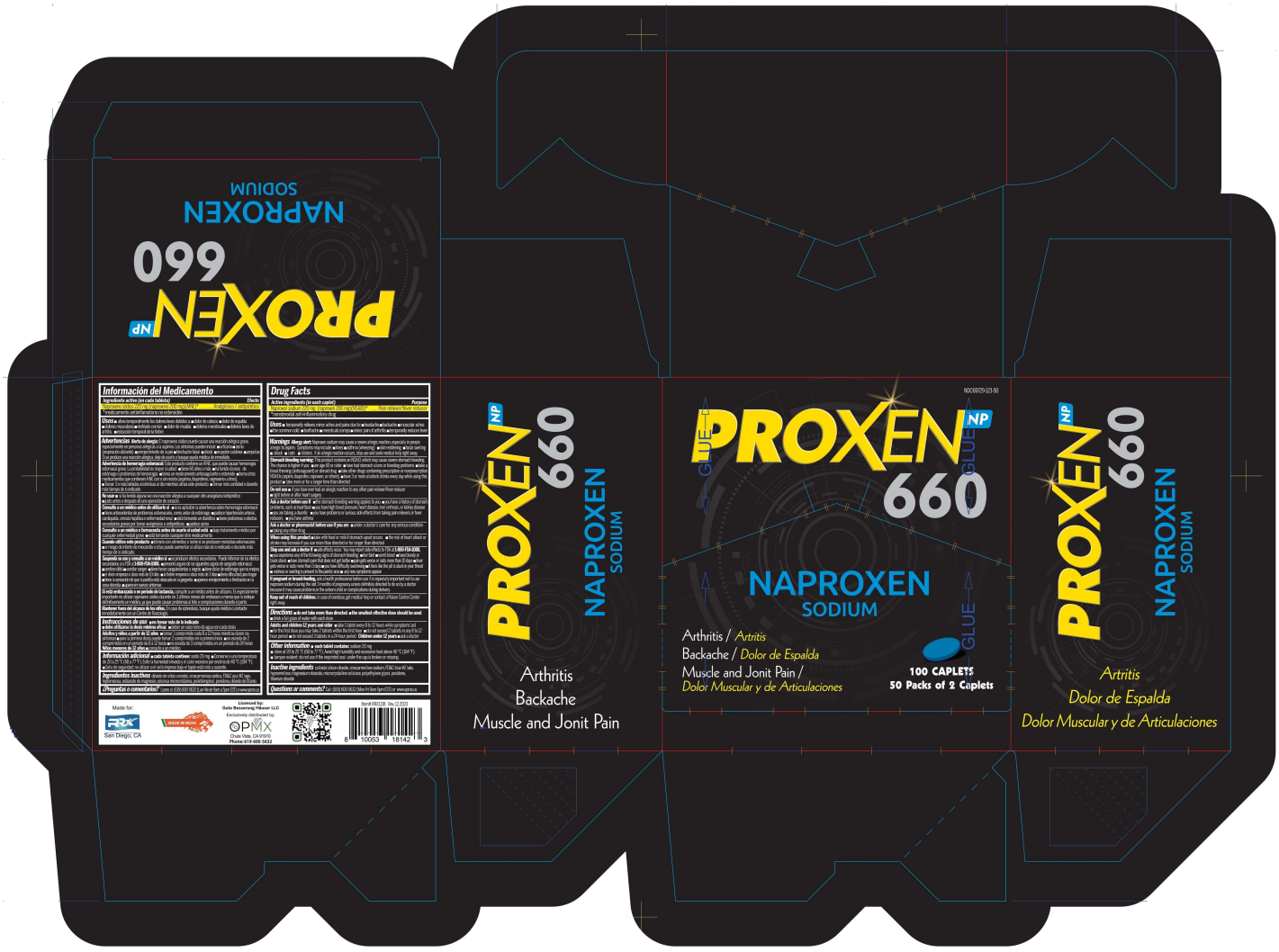
NAPROXEN SODIUM

Arthritis/Artritis

Backache/Dolor de Espalda

Muscle and Joint Pain/ Dolor Muscular y de Articulaciones

100 Caplets



PROXEN NP 660

naproxen sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69729-123
Route of Administration	ORAL		

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

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FD&C BLUE NO. 2 ALUMINUM LAKE (UNII: 4AQJ3LG584)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics

Color	blue (Light Blue)	**Score**	no score
Shape	OVAL (Capsule-Shaped)	**Size**	12mm
Flavor		**Imprint Code**	220
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-123-12	1 in 1 CARTON	11/07/2023	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69729-123-24	2 in 1 CARTON	11/16/2023	
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:69729-123-50	50 in 1 CARTON	11/07/2023	
3		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	11/07/2023	

Labeler - OPMX LLC (029918743)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Limited		860316511	manufacture(69729-123) , label(69729-123) , pack(69729-123)