NAPROXEN SODIUM- naproxen sodium tablet
Pharmacy Value Alliance, LLC

Naproxen Sodium Tablets USP 220 mg (Caplets)

Active Ingredient

(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

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 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 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 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

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

■ store at 20 - 25°C (68 to 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.

J50313A
1+9/16 x 1+9/16 x 3

Note: Ensure that the unvarnished area is not less than the minimum area specified on this document

Note: Ensure that the unfinished area is not less than the minimum area specified on this document.

GRANULES	JOB INFORMATION	HISTORY				COLORS	
	ITEM#:PV_Nap_Cap_24ct_IFC_India_R1 CAD#: J50313A	AS	Version# 1 Printed 3-24-15			4/COLOR PRO PMS 277 PMS 283S Pro Blue PMS 072 Q.C. _____	Die line UPC Code Measurement Info. Coating Free
		AS	Rev-1:	AS	Rev-6:		
		AS	Rev-2:	AS	Rev-7:		
		AS	Rev-3:		Rev-8:		
		AS	Rev-4:		Rev-9:		
		AS	Rev-5:		Rev-10:		

GRANULES ARTWORK APPROVAL (THIS PROOF MUST BE SIGNED AND RETURNED) Job will not be released for production unless signed off by the below

Approver	Name (print)	Signature	Date
OTC Marketing			
Packaging Engineering			
Regulatory Affairs			
Quality Assurance			

ATTENTION: PLEASE PROOFREAD CAREFULLY

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DIE GIFC001

1.750 x 1.750 x 3.375 Flat

Note: Ensure that the unvarnished area is not less than the minimum area specified on this document.

GRANULES

JOB INFORMATION		HISTORY			COLORS
ITEM#: 300000019_CDC_Nap_Cap_50ct_UPC_India_R1		Version# 1			4COLOR PRO
		AS Printed: 3-24-15			PMS 277
CAD#: J50009A		AS Rev-1: 3-25-15	AS	Rev-6: 4-23-15	PMS 2935
		AS Rev-2: 3-27-15	AS	Rev-7: 6-12-15	Pro Blue
		AS Rev-3: 3-31-15		Rev-8:	PMS 072
		AS Rev-4: 4-6-15		Rev-9:	
		AS Rev-5: 4-14-15		Rev-10:	Q.C. _____

Dieline
UPC Code
Measurement Info.
Coating Area

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DIE GIFC001

1.750 x 1.750 x 3.375 Flat Note: Ensure that the unvarnished area is not less than the minimum area specified on this document.

GRANULES	JOB INFORMATION	HISTORY	COLORS
	ITEM#: 300000021_CDC_Nap_Cap_100ct_UFC_India_R2	Version# 2	4COLOR PRO
	CAD#: J50009A	Primary 9-10-15	PMS 277
		Rev-1: 10-15-15	PMS 2995
		Rev-2:	ProBlue
		Rev-3:	PMS 072
		Rev-4:	Q.C. _____
		Rev-5:	
		Rev-6:	
		Rev-7:	
		Rev-8:	
		Rev-9:	
		Rev-10:	

Dieline
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NAPROXEN SODIUM

naproxen sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-660
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**
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

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:68016-660-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	02/25/2016	
2	NDC:68016-660-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/25/2016	
3	NDC:68016-660-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	02/25/2016	

Labeler - Pharmacy Value Alliance, LLC (101668460)

Registrant - Granules USA, Inc (137098864)

Revised: 1/2021 Pharmacy Value Alliance, LLC