NAPROXEN ALL DAY RELIEF FOR PAIN- naproxen sodium 220 mg tablet
Allegiant Health

Drug Facts

Active ingredient

Naproxen sodium 220mg
(naproxen 200mg) (NSAID)*
*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

temporarily relieves minor aches and pains due to: ■ minor pain of arthritis ■ backache ■ headache ■ muscular aches ■ menstrual cramps ■ toothache ■ 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

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

■ 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 doctors care for any serious condition ■ taking any other drug

When using this product

take with food or milk if stomach upset occursthe 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

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 immediately

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 8-12 hour period do not exceed 3 tablets in a 24-hour period **Children under 12 years**: ask a doctor

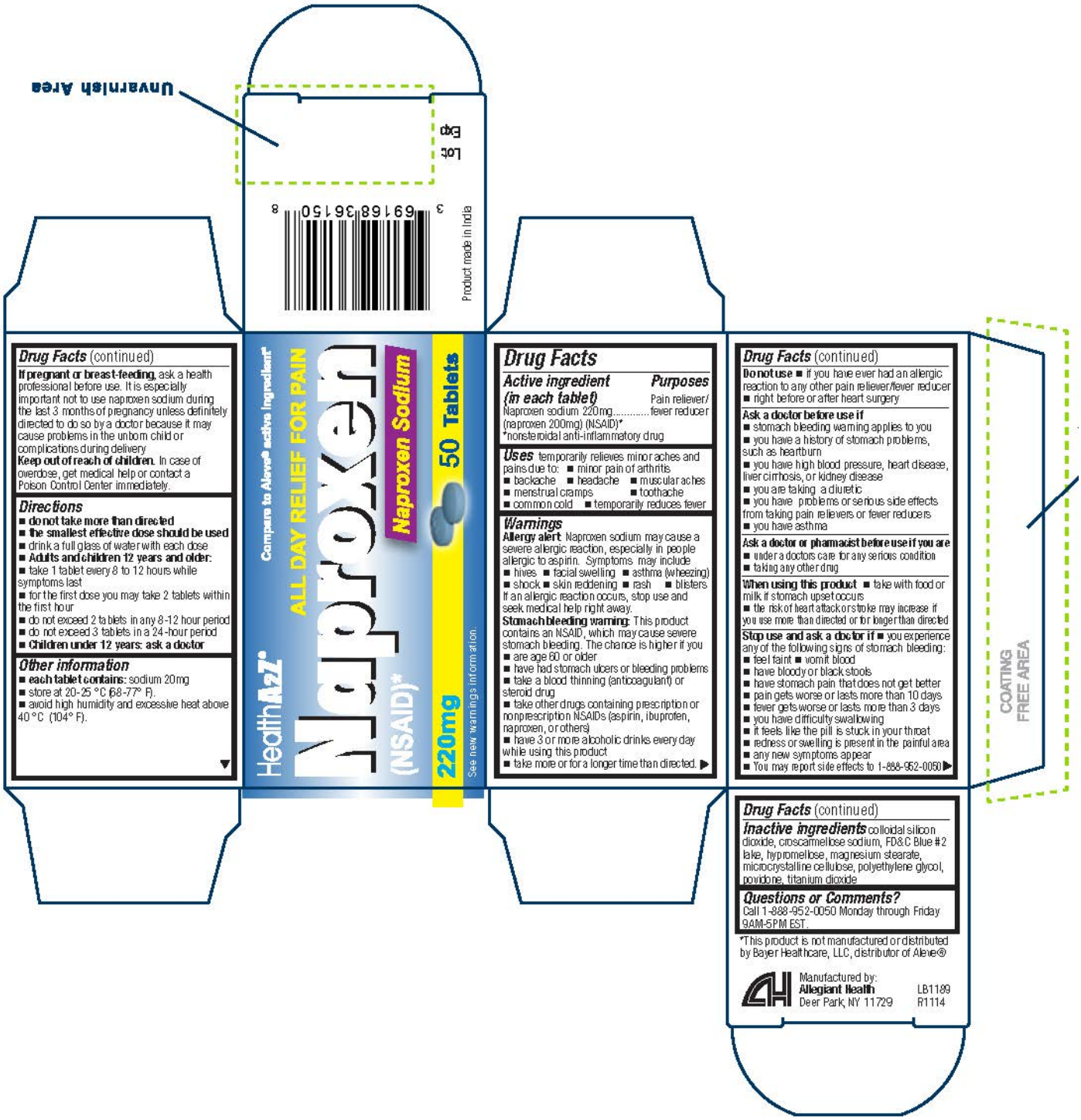
Other Information

each tablet contains: sodium 20mg store at 20-25 °C (68-77° F).■ avoid high humidity and excessive heat above 40 °C (104° F).**Do not use if tamper evident seal under bottle 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

Package/Label Principal Display Panel



NAPROXEN ALL DAY RELIEF FOR PAIN

naproxen sodium 220 mg tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69168-361
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	141
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-361-50	50 in 1 CARTON; Type 0: Not a Combination Product	12/23/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090545	12/23/2014	

Labeler - Allegiant Health (079501930)

Registrant - Allegiant Health (079501930)

Establishment

Name	Address	ID/FEI	Business Operations
Allegiant Health		079501930	ANALYSIS(69168-361) , MANUFACTURE(69168-361) , LABEL(69168-361) , PACK(69168-361) , RELABEL(69168-361) , REPACK(69168-361)

Revised: 12/2014 Allegiant Health