NAPROXEN SODIUM- naproxen sodium tablet
ADVANCED FIRST AID, INC.

ACTIVE INGREDIENT IN EACH TABLET-

Naproxen 200 mg

(naproxen 200 mg)(NSAID)*

*nonsteroidal anti-inflammatory drug

pain reliever/fever reducer

Uses: temporarily relieves minor aches and pains due to: • minor pain of arthritis • muscular aches • backache • menstrual cramps • headaches • 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

Stomach Bleeding Warning: This product contains 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 • 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 for 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 specifically 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 use more than directed • the smallest effective dose should be used • drink a full glass of water with each dose

Adults and children 12 years of age and older: • Take 1 tablet every 8 - 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.

Inactive Ingredients: FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, propylene glycol, povidone, talc, titanium dioxide

NAPROXEN SODIUM

naproxen sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67060-000
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN	200

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
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:67060-000-68	50 in 1 CARTON	04/09/2015	
1		1 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	ANDA090545	04/09/2015	

Labeler - ADVANCED FIRST AID, INC. (114477180)

Registrant - ADVANCED FIRST AID, INC. (114477180)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRA SEAL CORPORATION		085752004	pack(67060-000)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(67060-000)

Revised: 4/2015 ADVANCED FIRST AID, INC.