NAPROXEN- naproxen tablet
Alivio Medical Products, LLC

Drug Facts

Each capsule contains:

Naxproxen, ESP .....500 mg

Dosage and Use: For dosage recommendations

and other important prescribing information, read accompanying insert.

Store at 20 to 25 C (68 to 77 F); excursions

permitted to 15 to 30 C (59 to 86 F)[See

USP Controlled Room Temperature]

Dispense in well-closed, light-resistant containers

as defined in the USP.

BOXED WARNING

Cardiovascular Risk

-NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal.

-Naproxen as Naproxen Tablets, USP is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery (see WARNINGS).

Gastrointestinal Risk

-NSAIDs may cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration. and perforation of the stomach or intestines, which can be fatal.

DESCRIPTION

Naproxen, USP is a proprionic acid derivative related to the arylacetic acid group of nonsteroidal anti-inflammatory drugs.

CLINICAL PHARMACOLOGY

Pharmacodynamics - Naproxen is a nonsteroidal anti-inflammatory drug (NSAID) with analgesic and antipyretic properties.

CLINICAL STUDIES

General Information - Naproxen has been studied in patients with rheumatoid arthritis, osteoarthritis, juvenile arthritis, ankylosing spondylitis, tendonitis and bursitis, and acute gout.

INDICATIONS AND USAGE

Carefully consider the potential benefits and risks of naproxen tablets, USP and other treatments before deciding to sue naproxen tablets, USP.

CONTRAINDICATIONS

Naproxen tablets, USP are contraindicated in patients with known hypersensitivity to naproxen, USP.

WARNINGS

Cardiovascular Effects - Cardiovascular Thrombotic Events Clinical trials of several COX-2 selective and non-selective NSAIDs of up to three years duration have shown an increased risk of serious cardiovascular (CV)

thrombotic events, myocardial infarction, and stroke, which can be fatal.

PRECAUTIONS

General - Naproxen - containing products such as naproxen tablets, and other naproxen products should

not be used concomitantly since they all circulate in the plasma as the naproxin anion.

ADVERSE REACTIONS

Adverse reactions reported in controlled clinical trials in 960 patients treated for rheumatoid arthritis or osteoarthritis are listed below.

OVERDOSAGE

Symptoms and Signs Significant naproxen overdosage may be characterized by lethargy, dizziness, drowsiness, epigastric pain, abdominal discomfort, heartburn, indigestion, nausea, transient alterations in liver function,

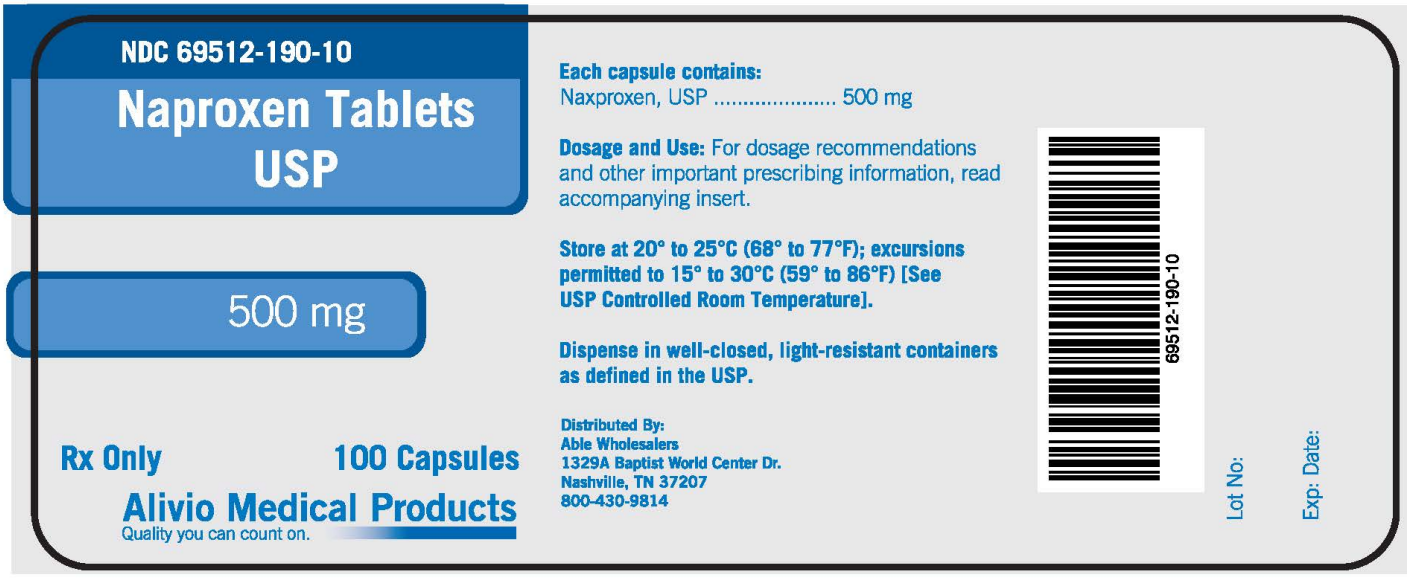
hypoprothrombinemia, renal dysfunction, metabolic acidosis, apnea, disorientation or vomiting.

DOSAGE AND ADMINISTRATION

Carefully consider the potential benefits and risks of naproxen tablets, USP and other treatment options before deciding to use naproxen tablets, USP.

MEDICATION GUIDE FOR NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)

(See the end of this Medication Guide for a list of prescription NSAID medicines.)



NAPROXEN

naproxen tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69512-190
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NAPROXEN (UNII: 57Y76R9ATQ) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN	500 mg in 500 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
POVIDONES (UNII: FZ989GH94E)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics			
Color	white (White)	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	IP190;500
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69512-190-10	100 in 1 BOTTLE		
1		500 mg in 1 CAPSULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075927	10/01/2015	

Labeler - Alivio Medical Products, LLC (079670828)

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