NAPROXEN SODIUM - naproxen sodium tablet, coated
Polygen Pharmaceuticals LLC

Naproxen Sodium Tablets, USP 220 mg

Active ingredient(s)

Naproxen Sodium 220 mg (naproxen 200 mg) (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/Fever reducer

Use(s)

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

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
- 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 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
- redness or swelling is present in the painful area
- any new symptoms appear
- you have difficulty swallowing
- it feels like the pill is stuck in your throat

Pregnancy/Breastfeeding

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 (1-800-222-1222).

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- to 12-hour period • do not exceed 3 tablets in a 24-hour period
children under 12 years:	• ask a doctor

Storage

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

Other information

- **each tablet contains:** sodium 20 mg
- side effects occur. You may report side effects to PolyGen at 1-888-291-7337 and/ or FDA at 1-800-FDA-1088.

Inactive ingredients

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

Questions or comments

1-800-291-7337

Principal Display Panel

NAPROXEN SODIUM TABLETS:

Carton PDP:

NDC: 52605-141-01

Compare to the active ingredient in Aleve®

ALL DAY PAIN RELIEF

NAPROXEN SODIUM TABLETS, USP 220 mg

PAIN RELIEVER/ FEVER REDUCER (NSAID)

STRENGTH TO LAST 12 HOURS

100 TABLETS

Bottle Label PDP:

NDC: 52605-141-01

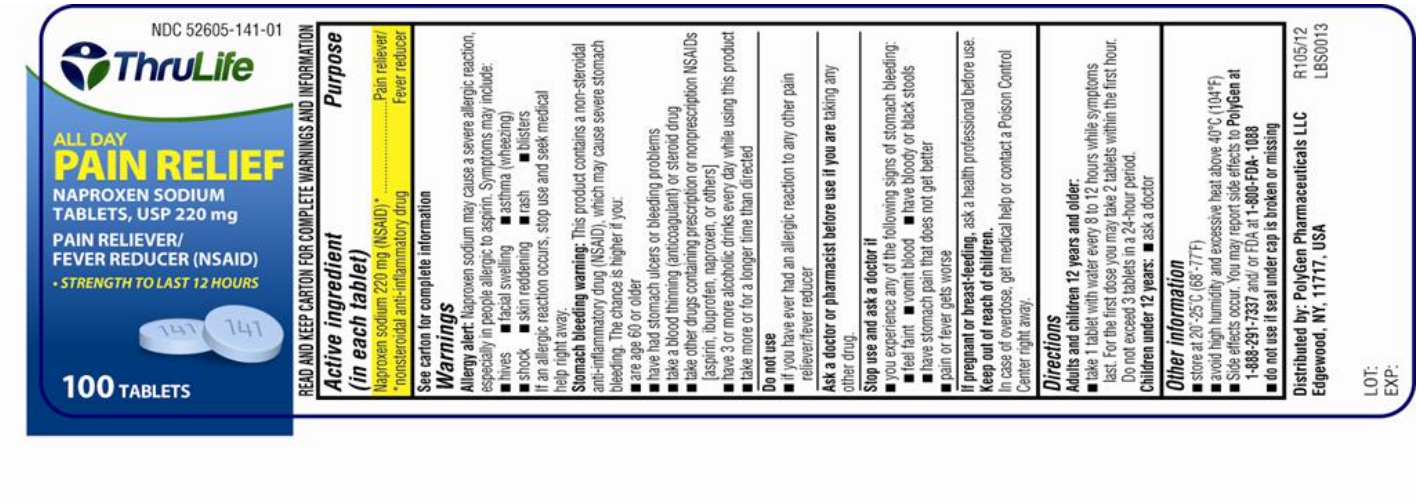
ALL DAY PAIN RELIEF

NAPROXEN SODIUM TABLETS, USP 220 mg

PAIN RELIEVER/ FEVER REDUCER(NSAID)

STRENGTH TO LAST 12 HOURS

100 TABLETS



NAPROXEN SODIUM CAPLETS:

Carton PDP:

NDC: 52605-144-01

Compare to the active ingredient in Aleve®

ALL DAY PAIN RELIEF
NAPROXEN SODIUM TABLETS, USP 220 mg
PAIN RELIEVER/ FEVER REDUCER (NSAID)

STRENGTH TO LAST 12 HOURS

100 CAPLETS (CAPSULE- SHAPED TABLETS)

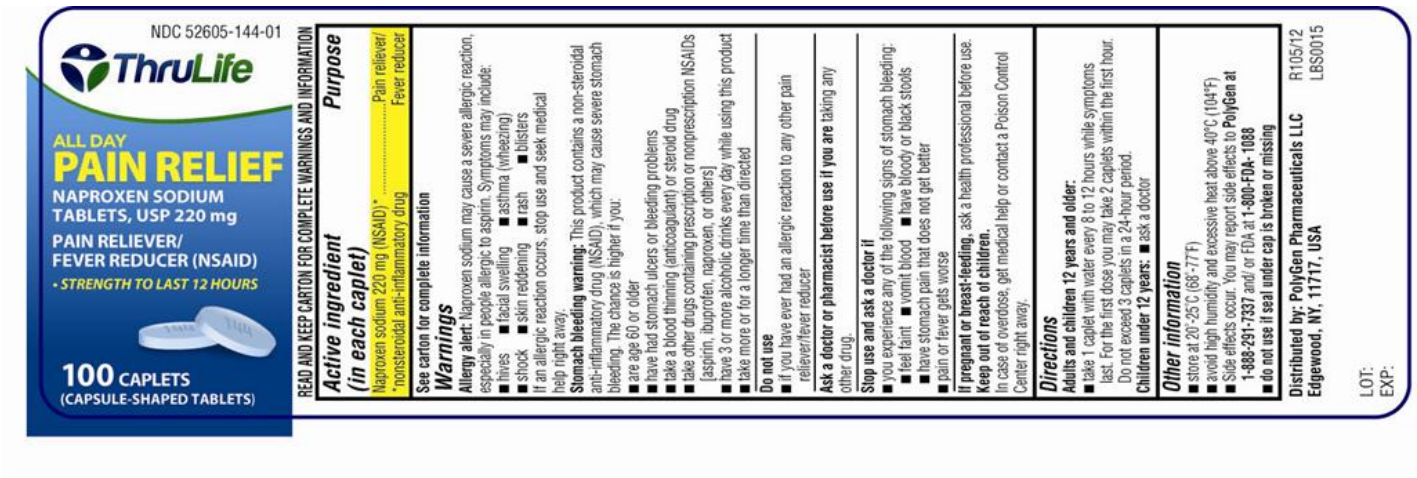
Bottle Label PDP:

NDC: 52605-144-01

ALL DAY PAIN RELIEF
NAPROXEN SODIUM TABLETS, USP 220 mg
PAIN RELIEVER/ FEVER REDUCER (NSAID)

STRENGTH TO LAST 12 HOURS

100 CAPLETS (CAPSULE- SHAPED TABLETS)



NAPROXEN SODIUM CAPLETS:

Carton PDP:

NDC: 52605-144-24

Compare to the active ingredient in Aleve®

ALL DAY PAIN RELIEF
NAPROXEN SODIUM TABLETS, USP 220 mg
PAIN RELIEVER/ FEVER REDUCER (NSAID)

STRENGTH TO LAST 12 HOURS

24 CAPLETS (CAPSULE- SHAPED TABLETS)

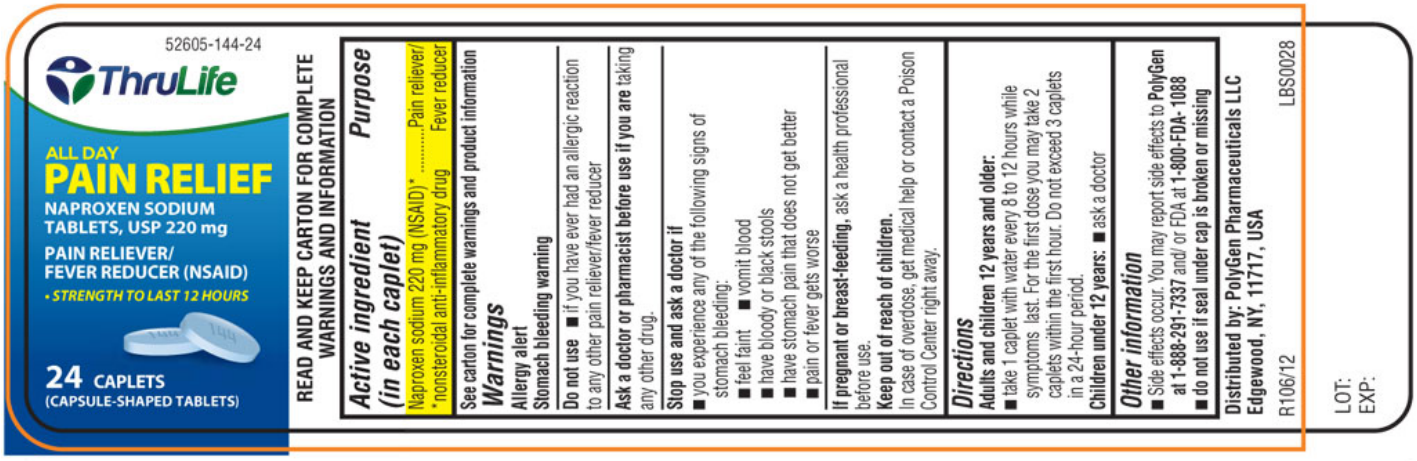
Bottle Label PDP:

NDC: 52605-144-24

ALL DAY PAIN RELIEF
NAPROXEN SODIUM TABLETS, USP 220 mg
PAIN RELIEVER/ FEVER REDUCER (NSAID)

STRENGTH TO LAST 12 HOURS

24 CAPLETS (CAPSULE- SHAPED TABLETS)



NAPROXEN SODIUM

naproxen sodium tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52605-141
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
COLLOIDAL 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)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	

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:52605-141-01	1 in 1 CARTON		
1		100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090545	06/11/2012	

NAPROXEN SODIUM

naproxen sodium tablet, coated

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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**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	BLUE	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	144
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52605-144-01	1 in 1 CARTON		
1		100 in 1 BOTTLE		
2	NDC:52605-144-24	1 in 1 CARTON		
2		24 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090545	11/13/2012	

Labeler - Polygen Pharmaceuticals LLC (962415720)

Registrant - Polygen Pharmaceuticals LLC (962415720)

Establishment

Name	Address	ID/FEI	Business Operations
Marksans Pharma Limited		925822975	MANUFACTURE(52605-144)

Revised: 6/2013 Polygen Pharmaceuticals LLC