

**PROPRINAL- ibuprofen capsules 200 mg capsule, liquid filled**  
**A-S Medication Solutions**

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**PROPRINAL**

***Active ingredient (in each capsule)***

**Solubilized Ibuprofen equal to**

**200 mg ibuprofen (NSAID)\***

(present as the free acid and potassium salt)

\* nonsteroidal anti-inflammatory drug

***Purpose***

Pain reliever/Fever reducer

***Uses:***

Temporarily relieves minor aches and pains due to:

- headache
- muscular aches
- backache
- minor arthritis pain
- the common cold
- toothache
- menstrual cramps

Temporarily reduces fever

***Warnings***

**Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- blisters
- shock
- facial swelling
- asthma (wheezing)
- rash
- skin reddening

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 pain reliever/fever reducer
- right before or after heart surgery

**Ask a doctor before use if**

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- 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

**Ask a doctor or pharmacist before use if you**

- are under a doctor's care for any serious condition
- take aspirin for heart attack or stroke (ibuprofen may decrease this benefit of aspirin)
- take any other drug

**When using this product** take with food or milk if stomach upset occurs

**Stop use and ask a doctor if**

- an allergic reaction occurs, seek medical help right away
- fever worsens or lasts more than 3 days
- pain worsens or lasts more than 10 days
- you have any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, or stomach pain that does not get better
- new symptoms occur
- redness or swelling is present
- you have symptoms of heart problems or stroke: chest pain, trouble breathing, weakness in one part or side of the body, slurred speech, or leg swelling

**If pregnant or breast-feeding,** ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in 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

adults and children 12 years and over:

- take 1 capsule every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 capsule, 2 capsules may be used
- do not take more than 6 capsules in 24 hours, unless directed by a doctor

children under 12 years of age : ask a doctor

## OTHER INFORMATION

### **Other information**

- **each capsule contains:** potassium 20 mg
- caplets enclosed in a sealed packet
- do not use if packet is torn, cut or open
- store at 59° to 86°F (15°-30°C)
- avoid excessive heat and humidity

**Inactive ingredients** Ammonium hydroxide, FD&C green #3, gelatin, iron oxide black, medium chain triglycerides, polyethylene glycol, propylene glycol, potassium hydroxide, purified water, shellac, sorbitan monooleate, sorbitol sorbitan

## HOW SUPPLIED

Product: 50090-3507

NDC: 50090-3507-0 2 CAPSULE, LIQUID FILLED in a PACKET / 300 in a BOX

## IBUPROFEN CAPSULES



## PROPRINAL

ibuprofen capsules 200 mg capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-3507(NDC:50332-0130)
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)		IBUPROFEN	200 mg	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
SHELLAC (UNII: 46N107B71O)				
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)				
AMMONIA (UNII: 5138Q19F1X)				
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)				
FERROSOFERRIC OXIDE (UNII: XM0M87F357)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)				
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)				
SORBITOL (UNII: 506T60A25R)				
Product Characteristics				
Color	green	Score	no score	
Shape	CAPSULE	Size	19mm	
Flavor		Imprint Code	133	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-3507-0	300 in 1 BOX	07/18/2018	
1		2 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	ANDA079205		01/11/2017	

**Labeler** - A-S Medication Solutions (830016429)

## Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-3507)

