

# IBUPROFEN- ibuprofen tablet, film coated RPK Pharmaceuticals, Inc.

## IBUPROFEN 400 MG - 600 MG AND 800 MG TABLETS

### ibuprofen tablets 400 mg - 600 mg- 800 mg medguide

#### Medication Guide for Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

What is the most important information I should know about medicines called Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)?

NSAIDs can cause serious side effects, including:

- Increased risk of a heart attack or stroke that can lead to death. This risk may happen early in treatment and may increase:
  - with increasing doses of NSAIDs
  - with longer use of NSAIDs

Do not take NSAIDs right before or after a heart surgery called a “coronary artery bypass graft (CABG).”

Avoid taking NSAIDs after recent heart attack, unless your healthcare provider tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.

- Increased risk of bleeding, ulcers and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach and intestines:
  - anytime during use
  - without warning symptoms
  - that may cause death

The risk of getting an ulcer or bleeding increases with:

- past history of stomach ulcers, or stomach or intestinal bleeding with use of NSAIDs
- taking medicines called “corticosteroids”, “anticoagulants”, “SSRIs”, or “SNRIs”
- increasing doses of NSAIDs
- older age
- longer use of NSAIDs
- poor health
- smoking
- advanced liver disease
- drinking alcohol
- bleeding problems

NSAIDs should only be used:

- exactly as prescribed
- at the lowest dose possible for your treatment
- for the shortest time needed

What are NSAIDs?

NSAIDs are used to treat pain and redness, swelling, and heat (inflammation) from medical conditions such as different types of arthritis, menstrual cramps and other types of short-term pain.

Who should not take NSAIDs?

Do not take NSAIDs:

- if you have had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs
- right before or after heart bypass surgery.

Before taking NSAIDs tell your healthcare provider about all of your medical conditions, including if you:

- have liver or kidney problems
- if you have high blood pressure
- have asthma
- are pregnant or plan to become pregnant. Talk to your healthcare provider if you are considering taking NSAIDs during pregnancy. You should not take NSAIDs after 29 weeks of pregnancy.
- are breast feeding or plan to breast feed.

Tell your healthcare provider about all of the medicines you take, including prescription or over-the-counter medicines, vitamins or herbal supplements.

NSAIDs and some other medicines can interact with each other and cause serious side effects. Do not start taking any new medicine without talking to your healthcare provider first.

What are the possible side effects of NSAIDs?

NSAIDs can cause serious side effects, including:

See “What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?”

- new or worse high blood pressure
- heart failure
- liver problems including liver failure
- kidney problems including kidney failure
- low red blood cells (anemia)
- life-threatening skin reactions
- life-threatening allergic reactions
- Other side effects of NSAIDs include: stomach pain, constipation, diarrhea, gas, heartburn, nausea, vomiting, and dizziness.

Get emergency help right away if you get any of the following symptoms:

- shortness of breath or trouble breathing
- chest pain
- weakness in one part or side of your body
- slurred speech
- swelling of the face or throat

Stop taking your NSAID and call your healthcare provider right away if you get any of the following symptoms:

- nausea
- more tired or weaker than usual
- diarrhea
- itching

- itching
- your skin or eyes look yellow
- indigestion or stomach pain
- flu-like symptoms
- vomit blood
- there is blood in your bowel movement or it is black and sticky like tar
- unusual weight gain
- skin rash or blisters with fever
- swelling of the arms, legs, hands and feet

If you take too much of your NSAID, Call your healthcare provider or get medical help right away. These are not all the possible side effects of NSAIDs. For more information, ask your healthcare provider or pharmacist about NSAIDs. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**Other information about NSAIDs**

- Aspirin is an NSAID but it does not increase the chance of a heart attack. Aspirin can cause bleeding in the brain, stomach, and intestines. Aspirin can also cause ulcers in the stomach and intestines.
- Some NSAIDs are sold in lower doses without a prescription (over-the-counter). Talk to your healthcare provider before using over-the-counter NSAIDs for more than 10 days.

**General information about the safe and effective use of NSAIDs**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use NSAIDs for a condition for which it was not prescribed. Do not give NSAIDs to other people, even if they have the same symptoms that you have. It may harm them. If you would like more information about NSAIDs, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about NSAIDs that is written for health professionals.

This Medication Guide has been approved by the U.S. Food and Drug Administration.  
Revision: R01/16

Manufactured for:  
Time-Cap Labs, Inc.  
7 Michael Avenue,  
Farmingdale, NY 11735, USA

Manufactured by:  
Marksans Pharma Ltd.  
Plot No. L-82, L-83, Verna Indl. Estate,  
Verna, Goa-403 722, India

## HOW SUPPLIED

Product: 53002-3981

NDC: 53002-3981-1 10 TABLET, FILM COATED in a BOTTLE

NDC: 53002-3981-2 15 TABLET, FILM COATED in a BOTTLE

NDC: 53002-3981-3 30 TABLET, FILM COATED in a BOTTLE

NDC: 53002-3981-5 50 TABLET, FILM COATED in a BOTTLE

## IBUPROFEN TABLET, FILM COATED

The image shows several labels for Ibuprofen 600mg Tablets, USP. Key information includes:

- Product Name:** IBUPROFEN 600MG TABLETS, USP
- Strength:** 600MG
- Formulation:** TABLETS, USP
- Dosing Instructions:** TAKE 1 TABLET 3 TIMES A DAY OR AS DIRECTED.
- Warnings:** IMPORTANT: THIS DRUG IS A NONSTEROIDAL ANTI-INFLAMMATORY DRUG. TAKE WITH FOOD OR MILK. READ THE DIRECTIONS CAREFULLY BEFORE USING.
- Barcode:** 53002-3981-3
- Lot Information:** LOT# 22491951000, EXP 11-30-2023, R#F 22491951000, FDA-3981
- Prescription Information:** BILLING NDC# 48483-0004-01, R#F 22491951000, 30 ea. IBUPROFEN 600MG TABLETS
- Discard By:** 11-30-2023
- Manufacturer:** Marksans Pharma Ltd., Verna, Goa-403 722, India

# IBUPROFEN

ibuprofen tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:53002-3981(NDC:49483-604)
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	800 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	123
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:53002-3981-2	15 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
2	NDC:53002-3981-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
3	NDC:53002-3981-5	50 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
4	NDC:53002-3981-1	10 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090796	12/30/2015	

**Labeler** - RPK Pharmaceuticals, Inc. (147096275)

## Establishment

Name	Address	ID/FEI	Business Operations
RPK Pharmaceuticals, Inc.		147096275	RELABEL(53002-3981) , REPACK(53002-3981)

Revised: 7/2023

RPK Pharmaceuticals, Inc.