# IBUPROFEN- ibuprofen capsule, liquid filled Camber Consumer Care. Inc.

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## 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:
  - o headache
  - o toothache
  - o backache
  - o menstrual cramps
  - o the common cold
  - o muscular aches
  - o minor pain of arthritis
- temporarily reduces fever

#### **Warnings**

Allergy alert: ibuprofen 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

**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 other 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
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

## When using this product

• take with food or milk if stomach upset occurs

## 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
- you have symptoms of heart problems or stroke:
  - . chest pain
  - . trouble breathing
  - . slurred speech
  - . leg swelling
  - . weakness in one part or side of body
- 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

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

#### Directions

- do not take more than directed
- the smallest effective dose should be used

adults and children 12 years and over:	<ul> <li>take 1 capsule every 4 to 6 hours while symptoms persist</li> <li>if pain or fever does not respond to 1capsule, 2 capsules may be used</li> <li>do not exceed 6 capsules in 24 hours, unless directed by a doctor</li> </ul>
children under 12 years:	• ask a doctor

## Other information

- each capsule contains: potassium 20 mg
- Read all warnings and directions before use. Keep carton.
- Store at 20-25°C (68-77°F)
- Avoid excessive heat above 40°C (104°F)

## **Inactive ingredients**

FD&C blue no. 1, FD&C yellow no. 6, gelatin, lecithin (soybean), medium-chain triglycerides, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan.

## **Questions or comments?**

call 1-888-588-1418

NDC 69230-146-52
Ibuprofen Capsules, 200mg
Pain Reliever/ Fever Reducer
(NSAID)
200mg, 160 SOFTGELS
Liquid-Filled Capsules



ibuprofen capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69230-146
Route of Administration	ORAL, ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
IBUPRO FEN (UNII: WK2XYI10 QM) (IBUPRO FEN - UNII: WK2XYI10 QM)	IBUPROFEN	200 mg

Inactive Ingredients			
Ingredient Name	Strength		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN (UNII: 2G86QN327L)			
LECITHIN, SO YBEAN (UNII: 1DI56 QDM62)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)			
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)			
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
SORBITAN (UNII: 6092ICV9RU)			

Product Characteristics				
Color	GREEN	Score	no score	
Shape	OVAL	Size	20 mm	
Flavor		Imprint Code	AT146	
Contains				

P	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69230-146-20	1 in 1 CARTON	05/01/2018	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69230-146-40	1 in 1 CARTON	05/01/2018	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69230-146-80	1 in 1 CARTON	05/01/2018	
3		80 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:69230-146-52	1 in 1 CARTON	05/01/2018	
4		160 in 1 BOTTLE; Type 0: Not a Combination Product		

<b>Marketing Infor</b>	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	

ANDA ANDA206999 05/01/2018

## Labeler - Camber Consumer Care. Inc. (079539968)

Revised: 4/2018 Camber Consumer Care. Inc.