

## **IBUPROFEN- ibuprofen capsule, liquid filled BJWC**

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### ***Drug Facts***

#### ***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
- toothache
- backache
- menstrual cramps
- the common cold
- muscular aches
- 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
  - weakness in one part or side of body
  - slurred speech
  - leg swelling

- 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 at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause delivery 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: 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 exceed 6 capsules in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

***Other information***

- each capsule contains: **potassium 20 mg**
- read all warnings and directions before use
- store at 20° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F). Protect from light.

***Inactive ingredients***

FD&C Blue #1, gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan and sorbitol

**For India Manufacturing Site:**

FD&C Blue #1, gelatin, polyethylene glycol, potassium hydroxide, purified water, sorbitan and sorbitol

***Questions or comments?***

call toll free **1-800-934-1204**

**DO NOT USE IF TAMPER-EVIDENT SEAL UNDER BOTTLE CAP IMPRINTED WITH "SEALED for YOUR PROTECTION" IS BROKEN OR MISSING.**

\*All trademarks are property of their respective owners. This product is not affiliated

with the makers/owners of Advil® LIQUI-GELS®.

MANUFACTURED FOR:

BIONPHARMA INC.

PRINCETON, NJ 08540

DISTRIBUTED BY:

BJ'S WHOLESALE CLUB, INC.

350 CAMPUS DRIVE

MARLBOROUGH, MA 01752

800-BJS-CLUB

BJ # 228163 V01

L0000799

R0324

**For India Manufacturing Site:**

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350 CAMPUS DRIVE

MARLBOROUGH, MA 01752

800-BJS-CLUB

BJ # 228163 V01

Code: TN/DRUGS/TN/25/00074

**MADE IN INDIA**

L0000955

R0125

P3262/00/25

**300's bottle label**

**Compare to the active ingredient in Advil® LIQUI-GELS®\***

berkley jensen®

**IBUPROFENCAPSULES, 200mg**

**PAIN RELIEVER/FEVER REDUCER (NSAID)**

Actual Size

300SOFTGELS\*\*

\*\*LIQUID FILLED CAPSULE



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**Drug Facts**

**Active ingredient (in each capsule)**  
Solubilized ibuprofen (NSAID) 200 mg (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  toothache  backache  menstrual cramps  
 the common cold  muscular aches  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

MANUFACTURED FOR:  
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PRINCETON, NJ 08540

DISTRIBUTED BY:  
BJS WHOLESALE CLUB, INC.  
350 CAMPUS DRIVE  
MARLBOROUGH, MA 01752  
800-BJS-CLUB

Lot No. **8867008149** 5  
Exp. Date: **BJF 228163 V01 L0000799**

PEEL HERE

**Drug Facts (continued)**

**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 the 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  weakness in one part or side of body  slurred speech  leg swelling  
 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 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.

**Directions**  
 do not take more than directed  
 the small red cap 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 exceed 6 capsules in 24 hours, unless directed by a doctor  children under 12 years: ask a doctor

**Other information**  
 each capsule contains: potassium 20 mg  
 read all warnings and directions before use  
 store at 20° to 25°C (68° to 77°F)  
 avoid excessive heat above 40°C (104°F). Protect from light.

**Inactive ingredients**  
FD&C Blue #1, gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan and sorbitol

**Questions or comments?** call toll-free 1-800-235-2466

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300's bottle label-Made In India

Compare to the active ingredient in Advil ® LIQUI-GELS ®\*

berkley jensen ®

I BUPROFENCAPSULES, 200mg

PAIN RELIEVER/FEVER REDUCER (NSAID)

Actual Size

300SOFTGELS\*\*

\*\*LIQUID FILLED CAPSULE

(MADE IN INDIA)

Compare to the active ingredient in Advil® LIQUID-GELS®



# IBUPROFEN

CAPSULES, 200mg

**PAIN RELIEVER/FEVER REDUCER (NSAID)**



Actual Size  
**300 SOFTGELS\*\***

\*\*LIQUID FILLED CAPSULES

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Sulfalized ibuprofen equal to 200 mg ibuprofen (NSAID)\*  
\*nonsteroidal anti-inflammatory drug

**Purpose**  
Pain reliever/Fever reducer

**Uses**  
temporarily relieves minor aches and pains due to:  
 ■ headache ■ toothache ■ backache ■ menstrual cramps  
 ■ the common cold ■ muscular aches ■ 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  
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**Do not use** ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer ■ right before or after heart surgery

MANUFACTURED FOR:  
BIONPHARMA, INC.  
PRINCETON, NJ 08540  
B.J.# 228163 V01 L0000955



DISTRIBUTED BY:  
B.J.'S WHOLESAL CLUB, INC.  
350 CAMPUS DRIVE  
MARLBOROUGH, MA 01752  
800-BUS-CLUB  
Cook, TN/DRUGS/TW6500074 Lot No.

Exp. Date: P3262/00/25

MADE IN INDIA

PEEL HERE

Non Varnish Area

**Drug Facts (continued)**

**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**  
 ■ 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 ■ weakness in one part or side of body ■ slurred speech ■ leg swelling  
 ■ pain gets worse or lasts more than 10 days  
 ■ fever gets worse or lasts more than 3 days  
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**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 exceed 6 capsules in 24 hours, unless directed by a doctor  
 ■ children under 12 years: ask a doctor

**Other information**  
 ■ each capsule contains: potassium 20 mg  
 ■ read all warnings and directions before use  
 ■ store at 20° to 25°C (68° to 77°F)  
 ■ avoid excessive heat above 40°C (104°F). Protect from light.

**Inactive ingredients**  
 FD & C Blue #1, gelatin, polyethylene glycol, potassium hydroxide, purified water, sorbitan and sorbitol

**Questions or comments?** call toll-free 1-800-235-2466

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T00129R0125

<b>IBUPROFEN</b> ibuprofen capsule, liquid filled			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68391-212
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	IBUPROFEN (UNII: WK2XY10QM) (IBUPROFEN - UNII:WK2XY10QM)	IBUPROFEN	200 mg
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>
	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
	GELATIN (UNII: 2G86QN327L)		

<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

<b>Product Characteristics</b>			
<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	IB1
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68391-212-83	300 in 1 BOTTLE; Type 0: Not a Combination Product	08/14/2019	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078682	08/14/2019	

**Labeler - BJWC** (159082692)

**Registrant - Bionpharma Inc.** (079637826)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Patheon Softgels Inc.		002193829	manufacture(68391-212)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
ESJAY Pharma PRIVATE LIMITED		957309497	manufacture(68391-212)