

IBUPROFEN- ibuprofen capsule, liquid filled
XLCare Pharmaceuticals, Inc

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 style="list-style-type: none">• take 1 capsule every 4 to 6 hours while symptoms persist• if pain or fever does not respond to 1capsule, 2 capsules may be used• do not exceed 6 capsules in 24 hours, unless directed by a doctor
children under 12 years:	<ul style="list-style-type: none">• 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 1-866-495-1995

NDC 72865-132-16

Ibuprofen Capsules, 200mg

Pain Reliever/ Fever Reducer

(NSAID)

200mg, 160 SOFTGELS

Liquid-Filled Capsules



NDC 72865-132-16

Ibuprofen Capsules, 200 mg

Solubilized Ibuprofen Capsules, 200 mg Pain Reliever/Fever Reducer (NSAID)

160 CAPSULES**

****Liquid-filled Capsules**

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Uses ■ temporarily relieves minor aches and pains due to: headache, muscular aches, menstrual cramps, the common cold, backache, toothache, minor pain of arthritis.

■ temporarily reduces fever

Warnings

■ Ask your doctor before use if you are pregnant, under a doctor's care for a serious condition, age 60 or over, taking any other drug or have stomach problems.

■ This product 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. **Do not use** this product if you have ever had an allergic reaction to any pain reliever/fever reducer.

■ **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (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

Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.

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.

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. Each capsule contains: **potassium 20 mg**

Questions or comments? call 1-866-495-1995

Distributed by:

XLCare Pharmaceuticals, Inc.
242 South Culver Street, Suite 202
Lawrenceville, GA 30046, USA, Made in USA

Rev. 01/20

NO VARNISH

Lot: _____
Exp: _____

IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72865-132
Route of Administration	ORAL, 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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	20mm

Flavor		Imprint Code	AT146
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72865-132-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2020	
2	NDC:72865-132-40	40 in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2020	
3	NDC:72865-132-80	80 in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2020	
4	NDC:72865-132-16	160 in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206999	03/09/2020	

Labeler - XLCare Pharmaceuticals, Inc (080991142)