# IBUPROFEN- ibuprofen capsule, liquid filled BIG LOTS STORES, INC.

-----

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

# **Active Ingridient**

# (in each capsule)

Solubulised 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

# **Allergy Alert**

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

- hives
- facial sewlling
- asthama (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
- weakness in one part or side of body
- 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 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.

Keep out of reach of children.

#### Overdose

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

adult 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

### chlidren 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 1-877-770-3183



#### **IBUPROFEN**

ibuprofen capsule, liquid filled

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:50594-146 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg in 200	

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

Product Characteristics					
Color	green (Green Transparent oblong Capsule Filled with a clear colorless to green solution)	Score	no score		
Shape	OVAL (Oblong Capsule)	Size	19 mm		
Flavor		Imprint Code	AT146		
Contains					

ı	Packaging				
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
ı	1 NDC:50594-146-04	40 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2019		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206999	04/30/2019	

# **Labeler -** BIG LOTS STORES, INC. (017885351)

Revised: 12/2020 BIG LOTS STORES, INC.