IBUPROFEN- ibuprofen capsule, liquid filled PuraCap Pharmaceutical LLC

Ibuprofen Capsules (Liquid Filled), 200 mg

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 conditon
- 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 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: 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. Keep carton.
- store at 20°-25°C (68°-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

gelatin, medium-chain triglycerides, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan solution, and white ink

Questions or commonts ?

Call toll free: 1-855-215-8180

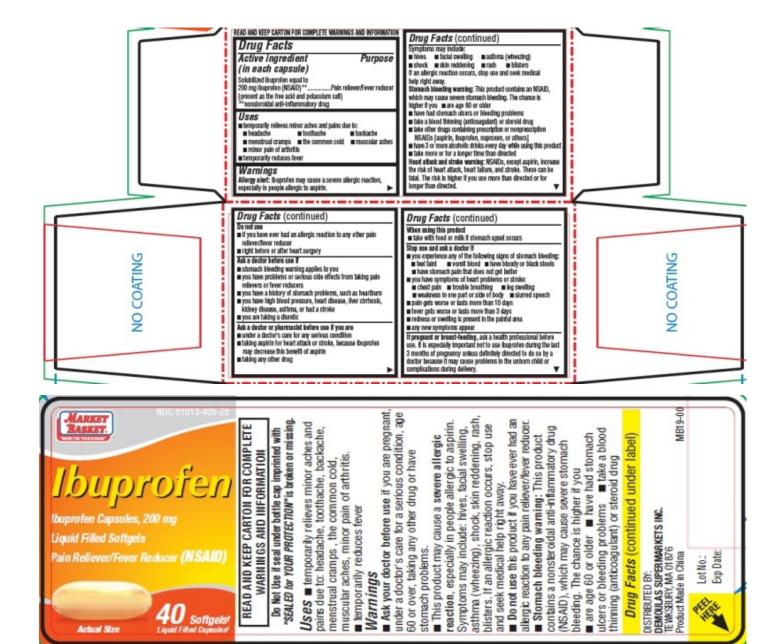
PRINCIPAL DISPLAY PANEL - 40ct

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

40 Liquid Filled Capsules

NDC 51013-405-25





 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.

Directions

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Each capsule contains: potassium 20 mg

Questions or comments?

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PRINCIPAL DISPLAY PANEL - 80ct

Ibuprofen Capsules, 200 mg

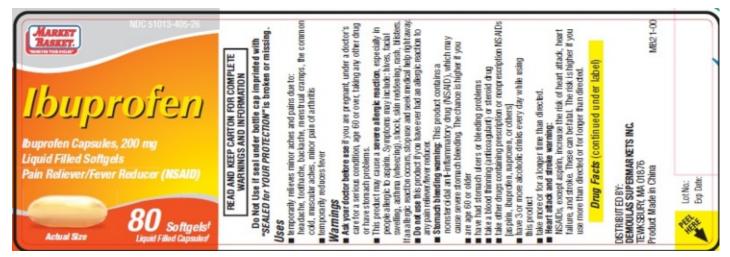
Pain Reliever/Fever Reducer (NSAID)

80 Liquid Filled Capsules

NDC 51013-405-26



READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION Drug Facts Active ingredient Purpose (in each capsule) Solubilized baprofon equal to 200 mg buporden (NSAID)**	Drug Facts (continued) Symptoms may include:	
Immortaite aches Immoranity reduces tever Warnings Altergy sint: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Drug Facts (continued) Be torture If you have ever had an allergic reaction to any other pain relever/inver reducer	 have 3 of more alcoholic drinks every day while using this product. lake more or for a longer time than directed Heart attack and stroke waning NSARDs, except aspirit, 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. Drug Facts (continued) Stop use and eak a doctor if you experience any of the following signs of stomach blocking: 	
injtit before or after heart surgery Ack a declor bleve use if stomach bleveling warning applies to you you have problems or serious side effects from taking you have problems or serious side effects from taking you have a history of stomach problems, such as heartburn you have a history of stomach problems, such as heartburn you have history disease, asffrma, or had a stroke you are baing a dioratic Ack a dector or pharmachit before use if you are under a doctor's care for any serious condition taking any other drug When using this product lake with lood or milk if stomach upset occurs	 There blocky or black stocis There storach pain that does not get better you have symptoms of heart problems or stocke: achest pain brouble breathing meakiness in one part or stocket achest pain brouble breathing and gets worse or lasts more than 10 days inder gets worse or lasts more than 10 days inder gets worse or lasts more than 10 days inder gets worse or lasts more than 10 days inder gets worse or lasts more than 10 days inder gets worse or lasts more than 10 days inder gets worse or lasts more than 10 days inder gets worse or lasts more than 10 days inder gets worse or lasts more than 10 days inder gets worse or lasts more than 10 days inder gets worse or lasts more than 10 days inder gets worse or lasts more than 10 days inder gets worse or lasts more than 10 days inder gets worse or lasts more than 10 days inder gets worse or lasts more than 10 days inder gets worse or lasts more than 10 days inder gets and the set of the gets of the set o	



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Questions or comments? call toll free: 1-855-215-8180

IBUPROFEN

ibuprofen capsule, liquid filled

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:51013-405

A	ctive Ingredien	t/Active Moiety							
		Ingredient Name		Basis of Strength		Strength			
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)				IBUPRO FEN		200 mg			
II	nactive Ingredie	nts							
		Ingredient Name			Strength				
G	ELATIN (UNII: 2G86	QN327L)							
Μ	EDIUM-CHAIN TRIC	GLYCERIDES (UNII: C9H2L21V7U)							
P	DLYETHYLENE GL	YCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)							
P	DTASSIUM HYDRO	XIDE (UNII: WZH3C48M4T)							
S	DRBITAN (UNII: 609	2ICV9RU)							
S	DRBITOL (UNII: 506	T60A25R)							
W	ATER (UNII: 059QF0	OKOOR)							
_									
P	roduct Characte	eristics							
Color		yellow (Clear Natural) Score		no score		ore			
Shape		CAPSULE (Oblong)	Size		18 mm				
Flavor		1	Imprint Code		P24				
С	ontains								
_									
P	ackaging								
#	Item Code	Package Description	Marketi	ng Start Date	Marketi	ng End Date			
1	NDC:51013-405-25	1 in 1 CARTON	07/14/2017	7					
1		40 in 1 BOTTLE; Type 0: Not a Combination Product							
2	NDC:51013-405-26	1 in 1 CARTON	07/14/2017	07/14/2017					
2		80 in 1 BOTTLE; Type 0: Not a Combination Product							
Marketing Information									
Marketing Category		y Application Number or Monograph Citation	n Market	rketing Start Date Marke		ing End Date			
ANDA		ANDA206568		07/14/2017		-			

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment								
Name	Address	ID/FEI	Business Operations					
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(51013-405), analysis(51013-405)					