IBUPROFEN PAIN RELIEVER/FEVER REDUCER- ibuprofen capsule, liquid filled
Amneal Pharmaceuticals LLC

Ibuprofen Capsules, liquid filled, 200 mg

OTC - 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

OTC - PURPOSE

Pain reliever/Fever reducer

INDICATIONS AND USAGE

- 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 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 or for a longer time than directed

OTC - DO NOT USE

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

OTC - ASK DOCTOR

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, or asthma
- you are taking a diuretic

OTC - ASK DOCTOR/PHARMACIST

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

OTC - WHEN USING

When using this product

- take with food or milk if upset stomach occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

OTC - STOP USE

Stop use and ask a doctor if

- you experience any of the follwing signs of stomach bleeding:
- feel faint

- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- 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

OTC - PREGNANCY OR BREAST FEEDING

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.

OTC - KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

DOSAGE AND ADMINISTRATION

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 20º to 25ºC (68º to 77ºF)
- avoid excessive heat above 40ºC (104ºF)

INACTIVE INGREDIENTS

D&C Yellow # 10, FD&C Blue # 1, gelatin, polyethylene glycol, potassium hydroxide, purified water, sorbitol

OTC – QUESTIONS OR COMMENTS?

Call **1-877-835-5472 Monday through Friday 9AM - 5PM EST**

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

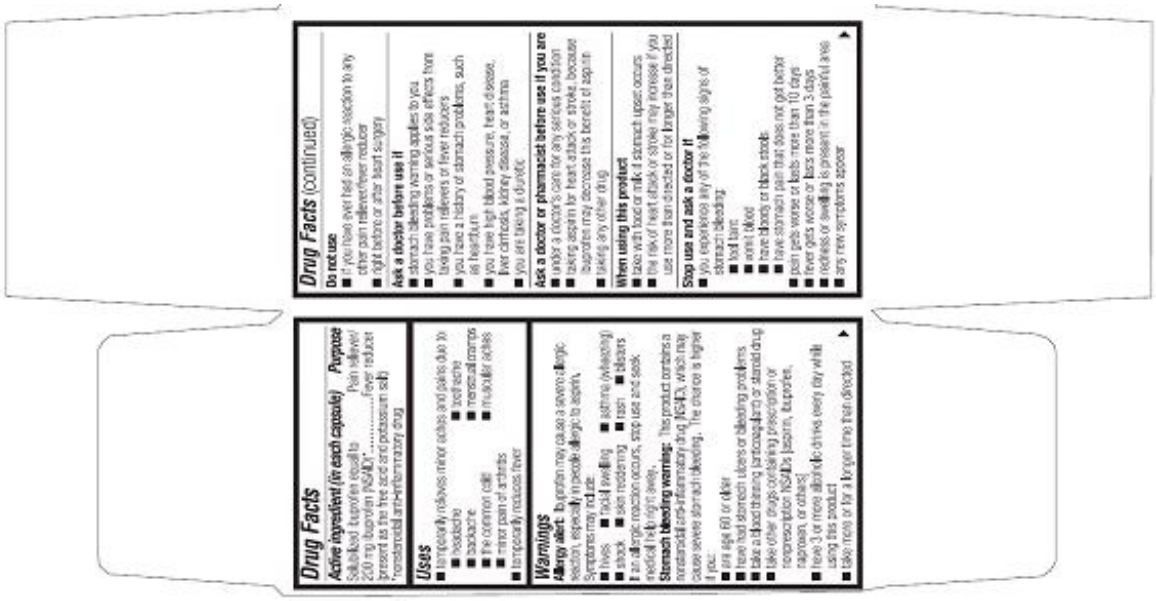
Do Not Use if printed foil under cap is broken or missing.

Distributed by: Amneal Pharmaceuticals

Glasgow, KY 42141

Rev. 08-2011

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



IBUPROFEN PAIN RELIEVER/FEVER REDUCER

ibuprofen capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65162-770
Route of Administration	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**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	turquoise	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	A;77
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65162-770-02	1 in 1 CARTON	12/23/2011	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:65162-770-69	1 in 1 CARTON	12/23/2011	
2		80 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:65162-770-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/23/2011	
4	NDC:65162-770-11	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/23/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202300	12/23/2011	

Labeler - Amneal Pharmaceuticals LLC (123797875)

Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals of New York, LLC		123797875	analysis(65162-770, 65162-770) , label(65162-770, 65162-770) , manufacture(65162-770, 65162-770) , pack(65162-770, 65162-770)

Revised: 12/2023 Amneal Pharmaceuticals LLC