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

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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 20° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F)

#### INACTIVE INGREDIENT

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. 03-2012

#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





#### IBUPROFEN PAIN RELIEVER/FEVER REDUCER

ibuprofen capsule, liquid filled

Product Information
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Product Type

HUMAN OTC DRUG LABEL

Item Code (Source)

NDC:65162-356

Route of Administration ORAL DEA Schedule

### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
IBUPRO FEN (IBUPRO FEN)	IBUPROFEN	200 mg

Inactive Ingredients		
Ingre	edient Name	Strength
FD&C BLUE NO. 1		
GELATIN		
POLYETHYLENE GLYCOL 400		
WATER		
PO TASSIUM HYDRO XIDE		
SORBITOL		

Product Characteristics			
Color	BLUE	Score	no score
Shape	CAPSULE	Size	18 mm
Flavor		Imprint Code	A356
Contains			

Pa	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 N	NDC:65162-356-02	1 in 1 CARTON		
1		20 in 1 BOTTLE		
2 N	NDC:65162-356-69	1 in 1 CARTON		
2		80 in 1 BOTTLE		
3 1	NDC:65162-356-50	500 in 1 BOTTLE		
4	NDC:65162-356-11	1000 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202300	03/29/2013	

## **Labeler** - Amneal Pharmaceuticals (123797875)

# **Registrant -** Amneal Pharmaceuticals (123797875)

Establishment			
Name	Address	ID/FEI	Business Operations
Amneal		931227777	ANALYSIS(65162-356), MANUFACTURE(65162-356), LABEL(65162-356),

Pharmaceuticals PACK(65162-356)

Revised: 11/2012 Amneal Pharmaceuticals