IBUPROFEN- ibuprofen tablet, coated
P & L Development, LLC

Drug Facts

Active ingredient (in each caplet)

Ibuprofen USP, 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches
  - minor pain of arthritis
  - toothache
  - backache
  - the common cold
  - menstrual cramps
- 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 an 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
- you have problems or serious side effects from taking pain reliever or fever reducers
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease asthma. or had a stroke
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under the doctor's care for any serious condition
- 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
  - have bloody or black stools
  - vomit blood
  - have stomach pain that does not get better
- you have symptoms of heart problem or stroke:
  - chest pain
  - slurred speech
  - leg swelling
  - trouble breathing
  - weakness in one part or side of body
- pain gets worse or last more than 10 days
- fever gets worse or last 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. (1-800-222-1222)

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**
- adults and children 12 years and older:
  - take 1 caplet every 4 to 6 hours while symptoms persist
  - if pain or fever does not respond to 1 caplet, 2 caplets may be used
  - do not exceed 6 caplets in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

Other information

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

Inactive ingredients

colloidal silicon dioxide, corn starch, iron oxide red,macrogol/PEG,polyvinyl alcohol-part. hydrolyzed, povidone (K-30), pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide,

Questions or comments?

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

Compare to the active ingredient in Advil®†

Ibuprofen

Tablets USP, 200 mg

Pain Reliever / Fever Reducer **(NSAID)**

coated caplets**

(**capsule-shaped tablets)

†This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributor of Advil®.

TAMPER-EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

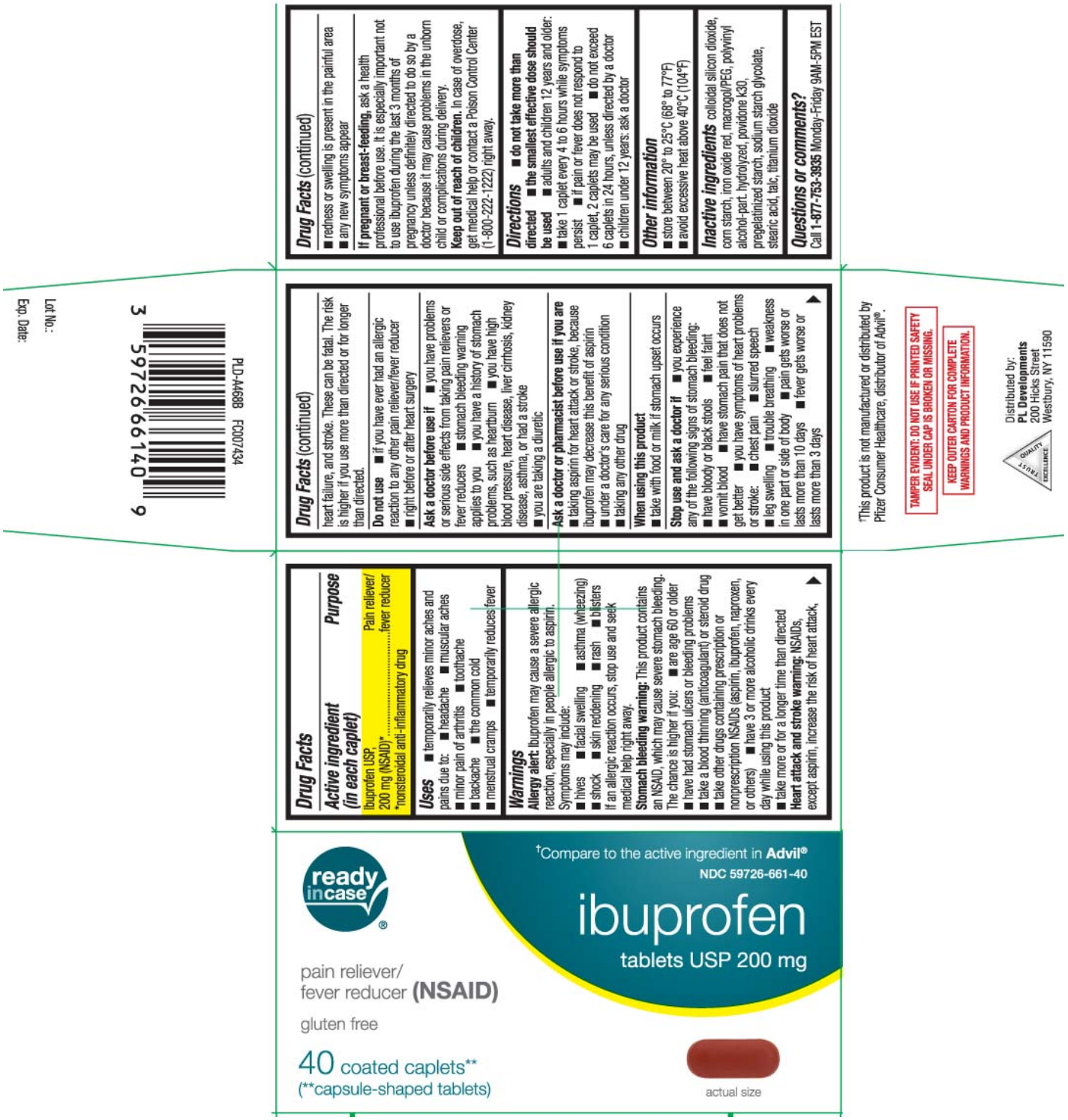
Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

Package Label



READYin CASE Ibuprofen 200 mg Caplets

IBUPROFEN

ibuprofen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59726-661
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

Color	brown	**Score**	no score
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	G2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-661-50	1 in 1 BOX	08/31/2017	08/31/2025
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:59726-661-40	1 in 1 BOX	08/31/2017	08/31/2025
2		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	08/31/2017	08/31/2025

Labeler - P & L Development, LLC (800014821)