

IBUPROFEN- ibuprofen tablet
Contract Pharmacy Services-PA

Ibuprofen 200 mg Tablets

DRUG FACTS

ACTIVE INGREDIENT (IN EACH TABLET)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever/fever reducer

USES

- temporarily relieves minor aches and pains due to:
- muscular aches
- minor pain of arthritis
- toothache
- backache
- the common cold
- menstrual cramps
- temporarily reduces fever

WARNINGS

Do not use

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

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 chances are 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

Ask a doctor before use if you are

- taking aspirin to prevent heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor’s care for any serious condition
- taking any other drugs

When using this product

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

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
- 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. (1-800-222-1222)

DIRECTIONS

- do not take more than directed
- the smallest effective dose should be used
- do not take longer than 10 days, unless directed by a doctor (see Warnings)
-

adults and children 12 years and older	take 1 tablet every 4 to 6 hours while symptoms persist if pain or fever does not respond to 1 tablet, 2 tablets may be used do not exceed 6 tablets in 24 hours, unless directed by a doctor
children under 12 years	ask a doctor

OTHER INFORMATION

- read all warnings and directions before use
- store at 20-25°C (68-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)

INACTIVE INGREDIENTS

colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, iron oxides, microcrystalline cellulose, polyethylene glycol, polysorbate 80, stearic acid, titanium dioxide

QUESTIONS OR COMMENTS?

Distributed by: SDA Laboratories Inc.
280 Railroad Avenue
Greenwich, Connecticut 06830, U.S.A.

Repackaged by:

Contract Pharmacy Services-PA
125 Titus Ave Suite 200
Warrington, PA 18976 USA

Original--08/2010--NJW

Package Label

IBUPROFEN

200 MG TAB #30



98100020000305

LOT# P62823

ID: 44 352

EXP: 06/11

BOA LABS

USUAL DOSAGE:
SEE INSERT

STORAGE
CONDITIONS: SEE
INSERT
(STORE AT
CONTROLLED ROOM
TEMPERATURE)

FILLED BY _____

CHECKED BY _____

Packaged By: Contract Pharmacy Services-PA
125 Titus Avenue, Suite #200, Warrington, PA 18976

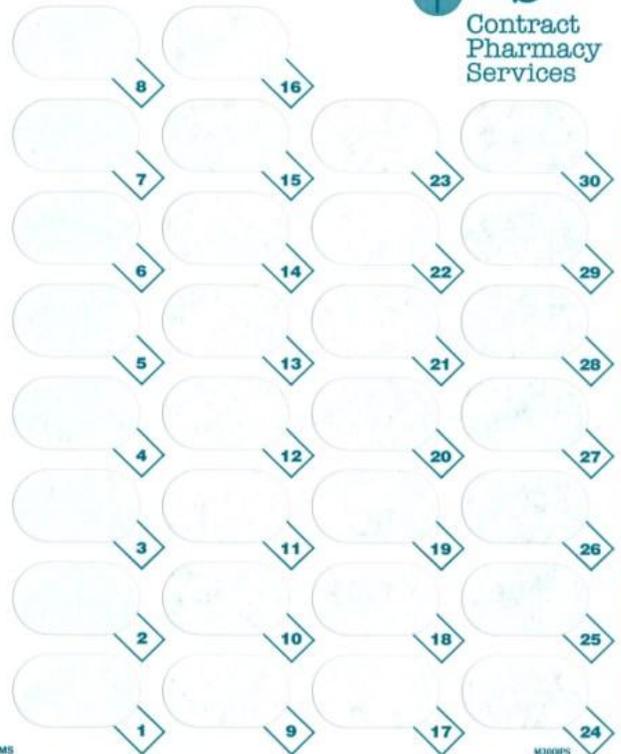
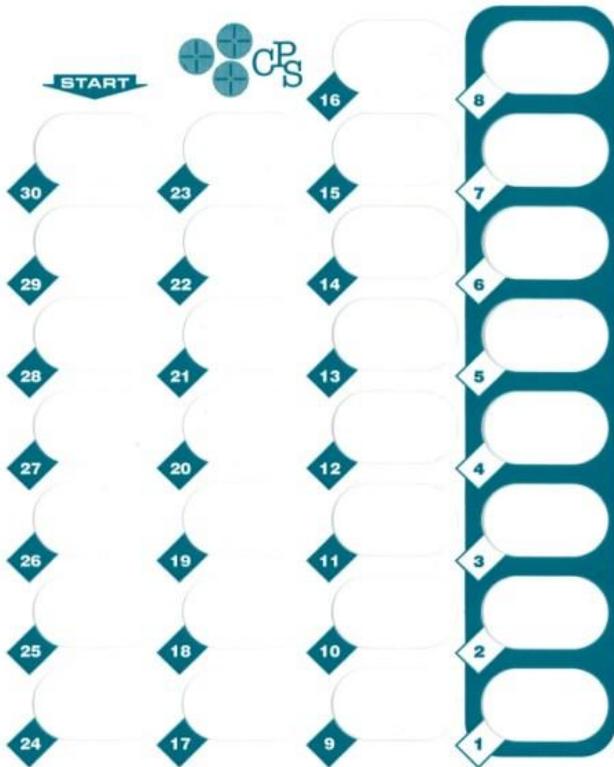
MED. _____

STRENGTH _____

EXP. DATE _____

MFG. _____

LOT NO. _____



CAUTION: This package NOT CHILD RESISTANT. Store this and all medications out of reach of children.

200 mg Tablets

IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67046-302(NDC:66424-995)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	44;352
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67046-302-30	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA072096	08/16/2010	

Labeler - Contract Pharmacy Services-PA (945429777)

Revised: 7/2010

Contract Pharmacy Services-PA