

IBUPROFEN - ibuprofen tablet
Physicians Total Care, Inc.

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 pain due to

- minor pain of arthritis
- headache
- toothache
- backache
- the common cold
- menstrual cramps
- muscular aches
- 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 non prescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks everyday while using this product
- take more or for a longer time 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 or asthma
- you are taking a diuretic

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

when using this product

- take 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 last for 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. **This package is not for households with young children.**

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**

- | |
|---|
| <ul style="list-style-type: none"> • take 1 tablet every 4 to 6 hours while symptoms |
|---|

Adults and children 12 years and older	<p>persist</p> <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • ask a doctor

other information

- store between 20°- 25°C (68°- 77°F)
- avoid high humidity and excessive heat above 40°C (104°F)

Inactive Ingredients:

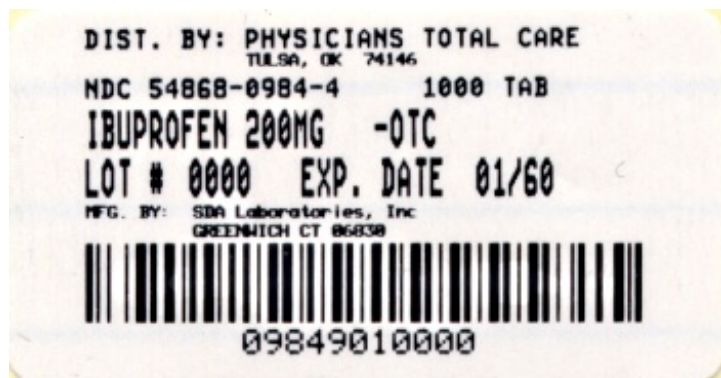
carnauba wax, colloidal silicon dioxide, croscarmellose sodium, DC yellow# 10, FDC blue# 2, FDC red# 40, FDC yellow# 6, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, polysorbate 80, red iron oxide, titanium dioxide

Questions? Adverse drug event call: (800)687-0176

*This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark ADVIL®.

Ibuprofen 200 mg (NSAID)*

NDC 54868-0984-4



Additional bar code label applied by:
Physicians Total Care, Inc.
Tulsa, Oklahoma 74146

IBUPROFEN

ibuprofen tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-0984(NDC:66424-996)	
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	
CARNAUBA WAX (UNII: R12CBM0EIZ)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYDEXTROSE (UNII: VH2XOU12IE)				
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	brown	Score	no score	
Shape	ROUND	Size	9mm	
Flavor		Imprint Code	2I	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-0984-4	1000 in 1 BOTTLE, PLASTIC		
2	NDC:54868-0984-3	100 in 1 BOTTLE, PLASTIC		
3	NDC:54868-0984-0	50 in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA075661	10/16/2007		

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 12/2011

Physicians Total Care, Inc.