IBUPROFEN PAIN RELIEVER/ FEVER REDUCER- ibuprofen 200 mg tablet
Chain Drug Consortium

Drug Facts

Active ingredient

Ibuprofen USP, 200mg (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 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 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

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 relievers or fever reducers ■ the 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 ■ you have asthma ■ you are taking a diuretic

Ask a doctor or pharmacist 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 drug

When using this product

take with food or milk if stomach upset occursthe 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
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

store between 20-25 °C (68-77° F). ■ Read all warnings and directions before use Do not use if seal under bottle cap is broken or missing.

Inactive Ingredients

Colloidal silicon dioxide, corn starch, FD&C Yellow #6 Aluminum Lake, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, talc, titanium dioxide and triacetin

Questions or Comments?

Call 1-888-952-0050
Monday through Friday 9AM – 5PM EST

Package/Label Principal Display Panel

IBUPROFEN PAIN RELIEVER/ FEVER REDUCER

ibuprofen 200 mg tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-030
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)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics			
Color	ORANGE	**Score**	no score
Shape	ROUND	**Size**	17mm
Flavor		**Imprint Code**	IBU200
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-030-14	50 in 1 CARTON; Type 0: Not a Combination Product	12/30/2014	
2	NDC:68016-030-16	100 in 1 CARTON; Type 0: Not a Combination Product	12/30/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA019355	12/30/2014	

Labeler - Chain Drug Consortium (101668460)

Registrant - Chain Drug Consortium (101668460)

Establishment

Name	Address	ID/FEI	Business Operations
Allegiant Health		079501930	LABEL(68016-030) , MANUFACTURE(68016-030) , PACK(68016-030) , RELABEL(68016-030) , REPACK(68016-030)

Revised: 12/2014 Chain Drug Consortium