IBUPROFEN- ibuprofen tablet
HART Health

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

IBUPROFEN

Active Ingredient (in each tablet): Ibuprofen (NSAID)* 200mg (*nonsteroidal anti-inflammatory drug)

Purpose: Pain Reliever / Fever Reducer

Uses: Temporarily relieves minor aches and pains due to
- headache
- muscular aches
- backache
- minor arthritis pain
- the common pain
- toothache
- 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
- rash
- shock
- facial swelling
- asthma (wheezing)
- skin reddening
- blisters

Stomach bleeding warning: This product contains an NSAID, which may cause stomach bleeding. The chance is higher if you:
- are age 60 or older
- have had stomach ulcers or bleeding problems
- take more or for a longer time than directed
- take a blood thinning (anticoagulant) or steroid drug
- have 3 or more alcoholic drinks every day while using this product
- take other drugs containing prescription or non-prescriptin NSAIDs (aspirin, ibuprofen, naproxen, or others)

Do not use
- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or afte rheart surgery

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history orstomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- taking any other drug containing an NSAID
- taking a blood thinning (anticoagulant) or steroid drug
- taking aspirin for heart attach or stroke (ibuprofen may decrease the benefit if aspirin)
- under a doctor's care for any serious condition

When using this product

- take with food or milk if stomach upset occurs
- long term continuous use may increase the risk of heart attack or stroke

Stop use and ask a doctor if

- an allergic reaction occurs, seek medical help right away
- fever gets worse or lasts more than 3 days
- pain gets worse or lasts more than 10 days
- redness or swelling is present in the painful area
- new symptoms occur
- you have any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, or stomach pain that does not get better

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

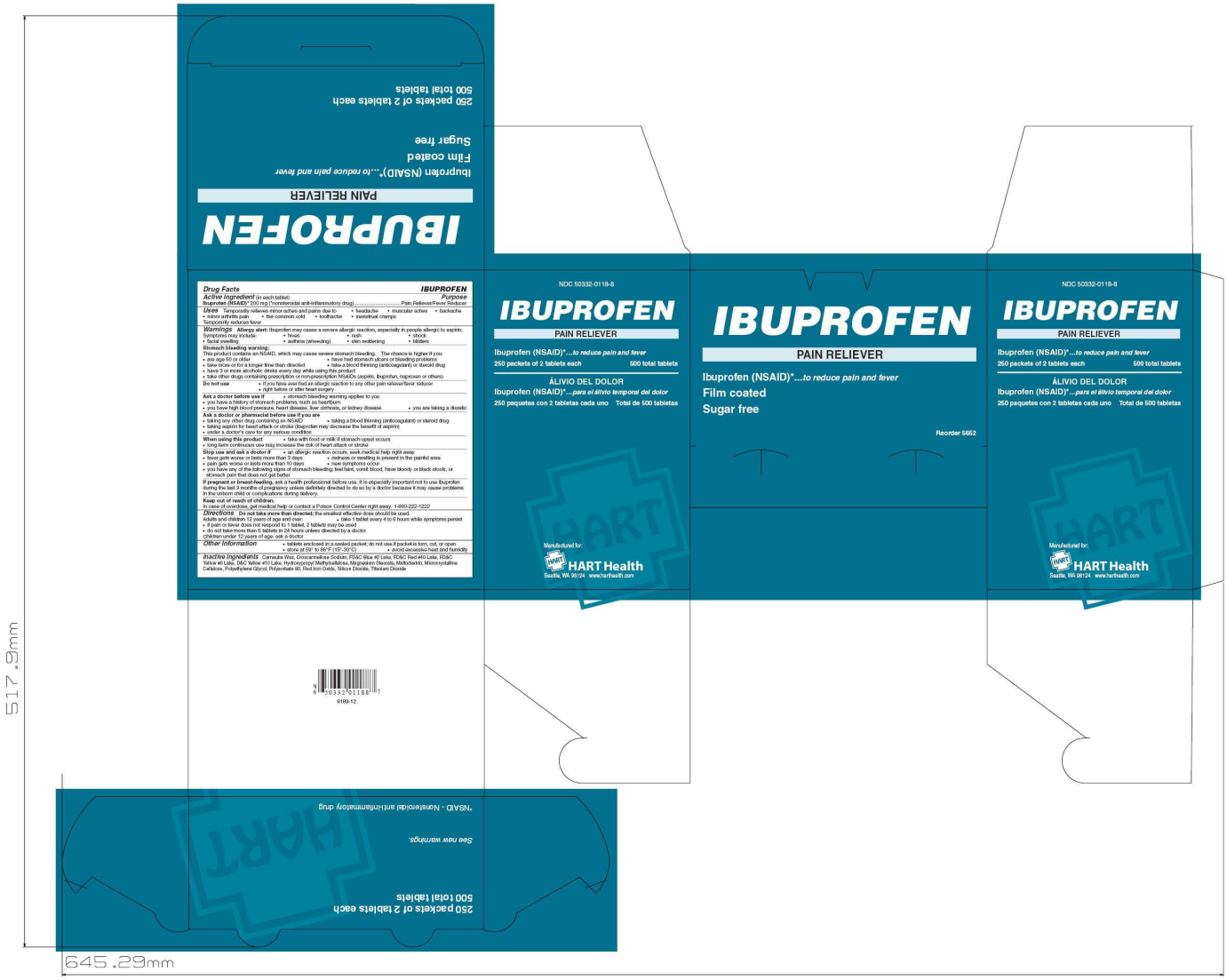
Directions: Do not take more than directed; the smallest effective dose should be used.

Adults and children 12 years of age and over:

- take 1 tablet every 4 hours while symptoms persist
- if pain or fever does not respond to 1 tabet, 2 tablets may be used
- do not take more than 6 tablets in 24 hours unless directed by a doctor

Children under 12 years of age: ask a doctor

Inactive Ingredients: Carnauba Wax, Croscarmellose Sodium, FD&C Blue #2 Lake, FD&C Red #40 Lake, FD&C Yellow #6 Lake, D&C Yellow #10 Lake, Hydroxypropyl Methylcellulose, Magnesiuum Stearate, Maltodextrin, Microcrystalline Cellulose, Polyethylene Glycol, Polysorbate 80, Red Iron Oxide, Silicon Dioxide, Titanium Dioxide



IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50332-0118
Route of Administration	ORAL	**DEA Schedule**	

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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	brown	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	IBU200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-0118-4	50 in 1 BOX, UNIT-DOSE		
1		2 in 1 PACKET		
2	NDC:50332-0118-7	125 in 1 BOX, UNIT-DOSE		
2		2 in 1 PACKET		
3	NDC:50332-0118-8	250 in 1 BOX, UNIT-DOSE		
3		2 in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	06/03/1987	

Labeler - HART Health (069560969)

Revised: 11/2012 HART Health