APROFEN REGULAR STRENGTH- ibuprofen tablet
A P J Laboratories Limited

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 USP, 200 mg (NSAID)

Pain reliever/fever reducer

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

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

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 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

CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS
STARCH, CORN

GELATIN

METHYLPARABEN
TITANIUM DIOXIDE

MAGNESIUM STEARATE

TALC
SODIUM STARCH GLYCOLATE TYPE A POTATO

SILICON DIOXIDE

APROFEN REGULAR STRENGTH
ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:46084-021
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
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	40 mg
STARCH, CORN (UNII: O8232NY3SJ)	20 mg
GELATIN (UNII: 2G86QN327L)	2 mg
METHYLPARABEN (UNII: A2I8C7HI9T)	3 mg
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	0.1 mg
MAGNESIUM STEARATE (UNII: 70097M6I30)	10 mg
TALC (UNII: 7SEV7J4R1U)	10 mg
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	20 mg
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	1 mg

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	200mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46084-021-26	500 in 1 BLISTER PACK		
2	NDC:46084-021-24	250 in 1 BLISTER PACK		
3	NDC:46084-021-23	100 in 1 BLISTER PACK		
4	NDC:46084-021-22	50 in 1 BLISTER PACK		
5	NDC:46084-021-31	2 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	02/21/2013	

Labeler - A P J Laboratories Limited (677378339)

Registrant - A P J Laboratories Limited (677378339)

Establishment

Name	Address	ID/FEI	Business Operations
A P J Laboratories Limited		677378339	manufacture(46084-021)