IBUPROFEN- ibuprofen tablet Granules India Limited

Ibuprofen Tablets, USP 200 mg

ACTIVE INGREDIENT(S)

Ibuprofen 200 mg (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 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

 \blacksquare 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

Heart attack and stroke warning: NSAIDs, except aspirin increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

DO NOT USE

 \blacksquare if you have ever had an allergic reaction to ibuprofen or 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
- \blacksquare you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma or had a stroke
- you are taking a diuretic

ASK A DOCTOR OR PHARMACIST BEFORE USE IF

- taking aspirin for 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 occurs

STOP USE AND ASK 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
- you have symptoms of heart problems or stroke:
- chest pain
- trouble breathing
- •weakness in one part or side of body
- slurred speech
- leg swelling
- 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 at 20 weeks or later in 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

	 take 1 caplet/tablet every 4 to 6 hours while symptoms persist if pain or fever does not respond to 1 caplet/tablet, 2 caplets/tablets may be used do not exceed 6 caplets/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).
- do not use if neck wrap or foil inner seal is broken or missing

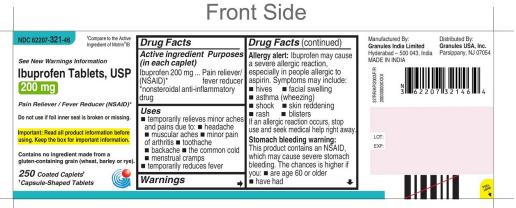
Inactive Ingredients

colloidal silicon dioxide, FD&C Yellow #6, maize starch, Povidone k30, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, sodium starch glycolate, stearic acid, talc titanium dioxide

QUESTIONS OR COMMENTS

Call 1-877-770-3183 weekdays 9:00 AM to 4:30 PM EST

PRINCIPAL DISPLAY PANEL

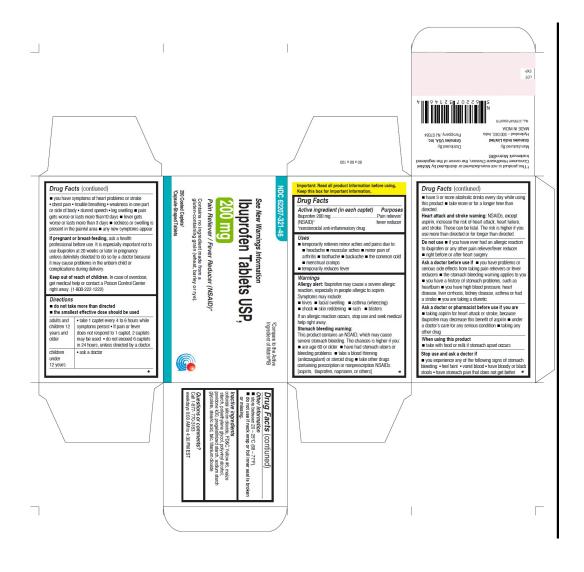


120 x 42 mm

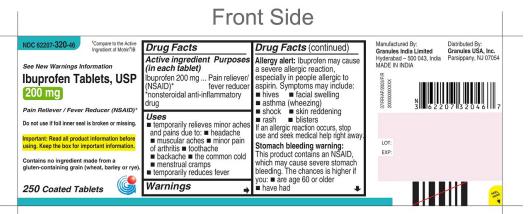
1st Layer Adhesive Side

while using this product "aka more of of marker you my orger time that and attroke warning: NSAIDs, sugger time that and attroke warning: NSAIDs, Heart attrack, heart fattack and attroke warning: NSAIDs, the stack, heart fattack and attroke warning: NSAIDs, and Heart attrack for any fatter each of the stack is high provide warning: NSAIDs, the stack is high the risk of heart attrack for attrack for any any intervention of the start. The risk is high provide warning: NSAIDs, and attrack for any out unsee what an allergic reaction to louptelen or any other or attract surgery. Do not uses — if you have ever had an allergic reaction to louptelen or any other or attra surgery. Ask a doctor before use if = you trave providems or problems or start surgery. Ask a doctor before use if a you have high blood in sup other attract and the state and reaction to the start problems. Ask a doctor before use if a you have high blood in sup out are a taking aspire to you are a taking a duration. You are a taking a duration. You are a taking a storke. You are a taking a storke. You are a taking a duration. You are a ta
--

				a	-	_ 71
Drug Facts (continued) than 3 days = redness or swelling is present in the partitul area a sury new symptoms spora the pregnant or breast-leeding, ask a health professional before use. It's especially mondarin not to use huppen at 20 weeks or later in pregnancy unless definitely directed to so by a doctor because it may cause problems in the unbom child or complications during delivery. Keep out of reach of children. In case of veredose, get medical help or condict a Poison Control Center right away.	INECTIONS do not take more than directed the smallest effective dose should be sed	 take 1 tablet every 4 to 6 hours while symptoms persist nor fever does not respond to 1 tablet, 2 tablets amy be used o on or exceed 6 captets in 24 hours, unless directed by a doctor. 	 ask a doctor 	Other Information ■ store between 20 – 25°C (88 – 77°F). ■ do not use if neck wrap or foil inner seal 's broken or missing.	Inactive ingredients olodial siloco doxide. FJSV *Blow #6, maze starch, polyethylene glycol, polyvinyl action, povidone K30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium doxide	Questions or comments? Call-1877-3703 weekayrs.200A.1383 Weekayr.200A.130 PM EST This pooluct is not manufactured or distributed by MoVel Consumer Header Dislon, the owner of the registred consumer Header Bo
Drug Facts (than 3 days = redn in the particulation are an in the particulation are an interpretent of the program of the problems in the ur during delivery.	 Directions do not take n the smallest used 	adults and children 12 years and older	children under 12 years	Other Informat ■ store between 20 – 2 ■ do not use if neck v is broken or missing.	nactive alloidal silico aize starch, cohol, povid odium starch anium dioxi	Zuestion all 1-877- 7 eekdays 9:1 his product is n naumer Health demark Motrin







120 x 42 mm

1st Layer Adhesive Side

a blood thiming anticoaguant) or steelod dreaseruption or nonprescription NSAIDs (assinin, libutorian, nancovar, or others) (assinin, libutorian, nancovar, or others) (assinin, libutorian, nanceaster had an Heart attack, heart failure, and stroke warning. NSAIDs, Mille using this product = lake more of of a Heart attack, heart failure, and stroke warning. NSAIDs, than of activity of the nance of Heart attack and stroke warning and tack, heart attack and stroke warning is to the stall. The risk is higher if you use more than directed or for ionger time han directed Do not uses = if you have ere had an allergic reaction to libutorien or any other attack mart surgery. Ask a doctor before use if = you have pain relevensher reducers = the pain relevensher reducers = the stomach bleeding warning applies to you are taking any other and pain relevensher reducers = the pain relevensher reducers = the stomach bleeding warning applies to you are stored. because libutorien may decrease this pain relevensher reducers = the stomach bleeding any other druge and stroke. because libutorien may decrease this pain relevensher reducers = the artiford and and the stores = the artiford and and a stroke = you are taking a duretic. Stop use and ask a doctor if a you experience any of the (howing signs of swelling = pain gets worse or lasts more + swelling = pain gets worse or lasts more + 10 days = fiever gets worse or lasts more +
--

Ibuprofen Tablets USP 200mg (Caplet)

Each film coated tablet contains: Ibuprofen USP 200 mg

Batch No.	: XXXXXXX	No. of Units	:	160,000	
Mfg.Dt.	: MM/YYYY	Gross Wt.	:	00.000 Kg	-
Exp.Dt.	: MM/YYYY	Tare Wt.	:	00.000 Kg	INDIA
NDC No.	: 62207-321-91	Net Wt.	:	00.000 Kg	
Mfg.Lic.No.	.: 37/RR/AP/2003/F/R	Drum number	:	000	of Origin:
Storage : Stor	re between 20 – 25 °C (68 – 77°F)				Country o
Caution : For	repacking only.				Cou

Caution : For repacking only.



(01)50362207321919(17)000000(10)XXXXXXX



Manufactured by: Granules India Limited

Sy.No.160/A, 161/E, 162, & 174/A, Gagillapur Village, Dundigal-Gandimaisamma Mandal, Medchal-Malkajgiri District - 500043, Telangana, INDIA

Ibuprofen Tablets USP 200 mg

Each film coated tablet contains: Ibuprofen USP 200 mg

Batch No.	: XXXXXXX	No. of Units	:	160,000
Mfg.Dt.	: MM/YYYY	Gross Wt.	:	00.000 K
Exp.Dt.	: MM/YYYY	Tare Wt.	:	00.000 K
NDC No.	: 62207-320-91	Net Wt.	:	00.000 K
Mfg.Lic.No	: 37/RR/AP/2003/F/R	Drum number	:	000



Product code : 700000001994

Kg

Kg

Kg

Storage : Store between 20 - 25 °C (68 - 77°F)

Caution : For repacking only.



Manufactured by: Granules India Limited Sy.No.160/A, 161/E, 162, & 174/A, Gagillapur Village,

Dundigal-Gandimaisamma Mandal, Medchal-Malkajgiri District - 500043, Telangana, INDIA

IBUPROFEN					
ibuprofen tablet					
Product Information					
Product Type	HUMAN OTC DRUG	ltem Code (Source)	NDC:62	207-320
Route of Administration	ORAL				
Active Increasiont/Active	Malaty				
Active Ingredient/Active	-				
Ingre	dient Name		Basis of Stre	ength	Strength
IBUPROFEN (UNII: WK2XYI10QM)	(IBUPROFEN - UNII:WK2XYI1)	DQM)	IBUPROFEN		200 mg
Inactive Ingredients					

00)189038320

Product code : 70000001995

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
STARCH, CORN (UNII: 08232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics						
Color	orange	Score	no score			
Shape	ROUND	Size	10mm			
Flavor		Imprint Code	G2			
Contains						

Pa	Packaging							
#	Item Code Package Description		Marketing Start Date	Marketing End Date				
1	NDC:62207-320- 41	24 in 1 BOTTLE; Type 0: Not a Combination Product	11/14/2019					
2	NDC:62207-320- 42	50 in 1 BOTTLE; Type 0: Not a Combination Product	11/14/2019					
3	NDC:62207-320- 43	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/14/2019					
4	NDC:62207-320- 46	250 in 1 BOTTLE; Type 0: Not a Combination Product	11/14/2019					
5	NDC:62207-320- 47	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/14/2019					
6	NDC:62207-320- 48	750 in 1 BOTTLE; Type 0: Not a Combination Product	11/14/2019					
7	NDC:62207-320- 49	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/14/2019					
8	NDC:62207-320- 91	160000 in 1 DRUM; Type 0: Not a Combination Product	11/14/2019					
9	NDC:62207-320- 89	10 in 1 BOTTLE; Type 0: Not a Combination Product	12/03/2020					
10	NDC:62207-320- 90	1700 in 1 BOTTLE; Type 0: Not a Combination Product	12/03/2020					

Marketing Information						
Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End Date						
ANDA	ANDA202312	11/14/2019				

IBUPROFEN ibuprofen tablet					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62	207-321
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
Ingredient Name			Basis of Stre	ength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)			IBUPROFEN		200 mg
Inactive Ingredients					
Ingredient Name				Strength	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
STARCH, CORN (UNII: 08232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDWIA)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	orange	Score	no score	
Shape	OVAL	Size	14mm	
Flavor		Imprint Code	G2	
Contains				

Packaging					
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:62207-321- 41	24 in 1 BOTTLE; Type 0: Not a Combination Product	11/14/2019		
2	NDC:62207-321- 42	50 in 1 BOTTLE; Type 0: Not a Combination Product	11/14/2019		
3	NDC:62207-321- 43	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/14/2019		
4	NDC:62207-321- 46	250 in 1 BOTTLE; Type 0: Not a Combination Product	11/14/2019		
5	NDC:62207-321- 47	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/14/2019		
6	NDC:62207-321- 48	750 in 1 BOTTLE; Type 0: Not a Combination Product	11/14/2019		
7	NDC:62207-321- 49	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/14/2019		
8	NDC:62207-321- 91	160000 in 1 DRUM; Type 0: Not a Combination Product	11/14/2019		
9	NDC:62207-321- 89	10 in 1 BOTTLE; Type 0: Not a Combination Product	12/03/2020		
10	NDC:62207-321- 90	1700 in 1 BOTTLE; Type 0: Not a Combination Product	12/03/2020		
	90	Product	12,03,2020		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202312	11/14/2019	

Labeler - Granules India Limited (915000087)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Ltd		918609236	analysis(62207-320, 62207-321) , label(62207-320, 62207-321) , manufacture(62207-320, 62207-321) , pack(62207-320, 62207-321)

Revised: 1/2023

Granules India Limited