IBUPROFEN- ibuprofen tablet **Granules India Limited**

Ibuprofen Tablets USP 200 mg (Brown)

Drug Facts

ACTIVE INGREDIENT

(in each tablet) Ibuprofen 200 mg (NSAID)*

PURPOSE

Pain reliever/fever reducer*nonsteroidal anti-inflammatory drug

USES

- temporarily relieves minor aches and pains due to:
- headache

- muscular aches
- minor pain of arthritis
- backache
- 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

- toothache
 - the common cold

■ 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 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

■ 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 lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling id 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	take a caplet every 4 to 6 hours while
years and older	symptoms persist
	■ if pain or fever dose not respond to 1 tablet,
	2 tablets may be used
	■ do not exceed 6 tablets in 24 hours , unless
	directed by a doctor
childer under 12 years	ask a doctor

OTHER INFORMATION

- store between 20-25°C (68-77°F)
- do not use if foil inner seal is broken or missing
- see end panel for lot number and expiration date

INACTIVE INGREDIENTS

colloidal silicon dioxide, dextrose monohydrate, hypromellose, iron oxide red, lactose monohydrate, lecithin, maize starch, maltodextrin, pregelatinized starch, povidone k30, sodium starch glycolate, stearicacid, sodium carboxymellose, triacetin, titanium dioxide

QUESTIONS OR COMMENTS?

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

M.L. 37/RR/AR/2003/F/R Manufactured By: Granules India Limited 2nd Floor 3rd Black, My Home hub Madhapur, Hyderabad – 500 081, India

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Ibuprofen Tablets, USP 200 mg (Round)

Each film coated tablet contains: Ibuprofen USP......200 mg

Batch No. : 365()348A	No. of Units	l	2,58,899 (80 kg approx.)	DIA
Mfg. Dt. : 10/2	019	Gross Wt.		90.210 kg	Country of Origin: INDIA
Exp. Dt. : 09/2	022	Tare Wt.		10.210 kg	Orig
NDC No. : 6220	07-365-16	Net Wet.	a la	80.000 kg	ry of
Mfg.Lic.No. : 37/F	R/AP/2003/F/R	Container No	;	001	unti
	veen 20-25°C (68-77°F); Controlled Room Temper	-	to	15°–30° C (59°–86° F).	ŭ
Caution : For repac	king only.	-			XXXX
GIL/PL/041C	FOR TRANSP Manufactured by: Granules Sy.No.160/A, 161/E, 162, 8 Dundigal-Gandimais amm Telangana, INDIA	174/A, Gagillapur Villag	i (ge	ed	Product Code: XXXXXXXXXXXXXXXXX

IBUPROFEN TABLETS USP, 200 mg (ROUND)

Each film coated tablet contains: Ibuprofen, USP 200 mg

Batch No. : XXXXXXX

No. of Tablets : 190,476 Tablets

Mfg.Dt. : MM-YYYY

Exp.Dt. : MM-YYYY

NDC No. : 62207-365-67

Mfg.Lic.No.: 37/RR/AP/2003/F/R

Storage : Store between 20 - 25°C (68 - 77°F). **Caution : For repacking only**

Country of Origin: INDIA



Manufactured by:

Granules India Limited

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

IBUPROFEN TABLETS USP, 200 mg (CAPLET)

Each film coated tablet contains: Ibuprofen, USP 200 mg

Batch No. : XXXXXXX

No. of Tablets : 190,476 Tablets

Mfg.Dt. : MM-YYYY

Exp.Dt. : MM-YYYY

NDC No. : 62207-366-67

Mfg.Lic.Na. : 37/RR/AP/2003/F/R

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

Telangana, INDIA

Caution : For repacking only

Country of Origin: INDIA



GIL/PL/041C

Manufactured by: Granules India Limited Sy.No.160/A, 161/E, 162, & 174/A, Gagillapur Village, Dundigal-Gandimaisamma Mandal, Medchal-Malkhajgiri District - 500043, Product code : F1180D7N

IBUPROFEN TABLETS, USP 200 mg (ROUND)

No. of Tablets : 175,000 Tablets

Each film-coated tablet contains: Ibuprofen, USP 200 mg

Batch No. : XXXXXXX

- Mfg.Dt. : MM/YYYY
- Exp.Dt. : MM/YYYY
- NDC No. : 62207-365-68
- Mfg.Lic.No.: 37/RR/AP/2003/F/R

Storage : Store at 20° - 25°C (68° - 77°F); excursions permitted between 15° - 30°C (59° - 86°F).

[See USP Controlled Room Temperature].

Caution : For repacking only

GIL/PL/041C



Manufactured by:

Granules India Limited

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

IBUPROFEN TABLETS, USP 200 mg (ROUND)

Each film-coated tablet contains: Ibuprofen, USP 200 mg

Batch No.	: XXXXXXX	No. of Tablets	:	175,000 Tablets
Mfg.Dt.	: MM/YYYY	Gross Wt.	:	00.000 Kg
Exp.Dt.	: MM/YYYY	Tare Wt.	:	00.000 Kg
NDC No.	: 62207-365-68	Net Wt.	:	00.000 Kg
Mfg.Lic.No	.: 37/RR/AP/2003/F/R	Container No.	:	000

Storage : Store at 20° - 25°C (68° - 77°F); excursions permitted between 15° - 30°C (59° - 86°F). [See USP Controlled Room Temperature].

Caution : For repacking only



(01)50362207365685(17)000000(10)XXXXXXX



GIL/PL/041C

Manufactured by:

Granules India Limited

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

Country of Origin: INDIA

Product code : F1079D3R



Product code : F1079D3R

IBUPROFEN TABLETS, USP 200 mg (CAPLET)

No. of Tablets : 175,000 Tablets

Each film-coated tablet contains: Ibuprofen, USP 200 mg

Batch No. : XXXXXXX

- Mfg.Dt. : MM/YYYY
- Exp.Dt. : MM/YYYY
- NDC No. : 62207-366-68
- Mfg.Lic.No.: 37/RR/AP/2003/F/R

Storage : Store at 20° - 25°C (68° - 77°F); excursions permitted between 15° - 30°C (59° - 86°F).

[See USP Controlled Room Temperature].

Caution : For repacking only

GIL/PL/041C



Manufactured by:

Granules India Limited

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

IBUPROFEN TABLETS, USP 200 mg (CAPLET)

Each film-coated tablet contains: Ibuprofen, USP 200 mg

Batch No.	: XXXXXXX	No. of Tablets	:	175,000 Tablet
Mfg.Dt.	: MM/YYYY	Gross Wt.	:	00.000 Kg
Exp.Dt.	: MM/YYYY	Tare Wt.	:	00.000 Kg
NDC No.	: 62207-366-68	Net Wt.	:	00.000 Kg
Mfg.Lic.No	.: 37/RR/AP/2003/F/R	Container No.	:	000

Storage : Store at 20° - 25°C (68° - 77°F); excursions permitted between 15° - 30°C (59° - 86°F). [See USP Controlled Room Temperature].

Caution : For repacking only



(01)50362207366682(17)000000(10)XXXXXXX



GIL/PL/041C

Manufactured by:

Granules India Limited

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



Product code : F1076D3R

Country of Origin: INDIA

Product code : F1076D3R

BUPROFEN							
Product Informa	ation						
Product Type		BULK INGREDIEN	IТ	Item Code	(Source)	NDC:62	207-365
Route of Administr	ation	NOT APPLICABLE	Ξ				
Active Ingredien	t/Active	Moiety					
	Ingrea	lient Name			Basis of St	rength	Strength
IBUPROFEN (UNII: WK2	XYI10QM) (I	BUPROFEN - UNII:	WK2XYI10	QM)	IBUPROFEN		200 mg
Inactive Ingredie	ents						
		Ingredien	t Name				Strength
STARCH, CORN (UNII:	08232NY35])					
POVIDONE K30 (UNII:	U725QWY32	X)					
STEARIC ACID (UNII: 4	ELV7Z65AP)						
SILICON DIOXIDE (UN	II: ETJ7Z6XB	U4)					
SODIUM STARCH GLY	COLATE T	PE A POTATO (UNII: 5850	6J3G2A2)			
HYPROMELLOSE 2208	B (100 MP/		P712K)				
TRIACETIN (UNII: XHX3	C3X673)						
LACTOSE MONOHYDF	RATE (UNII:	EWQ57Q8I5X)					
TITANIUM DIOXIDE (U	NII: 15FIX9V	2JP)					
FERRIC OXIDE RED (U	NII: 1K09F30	G675)					
DEXTROSE MONOHYD	DRATE (UNII	: LX22YL083G)					
LECITHIN, SOYBEAN (UNII: 1DI560	QDM62)					
MALTODEXTRIN (UNII:	7CVR7L4A2	D)					
CARBOXYMETHYLCEL	LULOSE S	DDIUM (UNII: K67	790BS311	.)			
Product Charact	eristics						
Color	red		Score			no score	
Shape	ROL		Size			10mm	
Flavor			Imprint	Code		G;2	
Contains							
Packaging							
# Item Code	Packa	ge Descriptio	on Ma	arketing Sta	art Date Ma	arketing	End Date
1 NDC:62207-365-24	48000 in 2	LBOX		1/2011			
2 NDC:62207-365-25	71000 in 3			1/2011			
3 NDC:62207-365-26	80000 in 3			1/2011			
4 NDC:62207-365-27	97000 in 2			1/2011			
5 NDC:62207-365-66	258000 in			1/2011			
6 NDC:62207-365-67	190476 in	1 DRUM	01/0	1/2011			
7 NDC:62207-365-80	258000 in			1/2011			

8 NDC:62207-365-68	175000 in 1 E	зох	01/01/2011			
9 NDC:62207-365-16	258899 in 1 [11/10/2019			
NDC.02207 505 10	250055 11 11		11/10/2015			
Marketing Inf	formatio	n				
Marketing	Applicatio	n Number or Mo	onograph	Marketing S	tart Ma	rketing End
Category		Citation		Date		Date
Export only				01/01/2011		
BUPROFEN						
buprofen tablet						
Product Informa	tion					
Product Type	BL	JLK INGREDIENT	ltem Co	ode (Source)	NDC:6	2207-366
Route of Administra	ation NC	OT APPLICABLE				
Active Ingredient	t/Active Mo	biety				
Active Ingredient		piety nt Name		Basis o	of Strength	Strengt
Active Ingredient	Ingredie	nt Name	XYI10QM)	Basis o	-	Strengtl 200 mg
	Ingredie	nt Name	XYI10QM)		-	-
IBUPROFEN (UNII: WK2)	Ingredie XYI10QM) (IBUF	nt Name	XYI10QM)		-	-
IBUPROFEN (UNII: WK2)	Ingredie XYI10QM) (IBUF	nt Name PROFEN - UNII:WK2)			-	200 mg
IBUPROFEN (UNII: WK2)	Ingredie XYI10QM) (IBUR ents	nt Name			-	-
IBUPROFEN (UNII: WK2)	Ingredie XYI10QM) (IBUF ents D8232NY3SJ)	nt Name PROFEN - UNII:WK2)			-	200 mg
IBUPROFEN (UNII: WK2) Inactive Ingredie STARCH, CORN (UNII: (Ingredie XYI10QM) (IBUR ents D8232NY3SJ) U725QWY32X)	nt Name PROFEN - UNII:WK2)			-	200 mg
IBUPROFEN (UNII: WK2) Inactive Ingredie STARCH, CORN (UNII: (POVIDONE K30 (UNII: (Ing red ie XYI10QM) (IBUF ents D8232NY3SJ) U725QWY32X) ELV7Z 65AP)	nt Name PROFEN - UNII:WK23			-	200 mg
IBUPROFEN (UNII: WK2) Inactive Ingredie STARCH, CORN (UNII: (POVIDONE K30 (UNII: (STEARIC ACID (UNII: 48	Ingredie XYI10QM) (IBUR ents D8232NY3SJ) U725QWY32X) ELV7Z65AP) I: ETJ7Z6XBU4)	nt Name PROFEN - UNII:WK2) Ingredient Na	ame		-	200 mg
IBUPROFEN (UNII: WK2) Inactive Ingredie STARCH, CORN (UNII: (POVIDONE K30 (UNII: (STEARIC ACID (UNII: 4E SILICON DIOXIDE (UNII	Ingredie XYI10QM) (IBUF ents D8232NY3SJ) U725QWY32X) ELV7Z 65AP) I: ETJ7Z 6XBU4) COLATE TYPE	nt Name PROFEN - UNII:WK2) Ingredient Na	ame 5856J3G2A2)		-	200 mg
IBUPROFEN (UNII: WK2) Inactive Ingredie STARCH, CORN (UNII: (POVIDONE K30 (UNII: (STEARIC ACID (UNII: 4E SILICON DIOXIDE (UNII SODIUM STARCH GLY(Ingredie XYI10QM) (IBUF ents D8232NY3SJ) U725QWY32X) ELV7Z65AP) I: ETJ7Z6XBU4) COLATE TYPE B (100 MPA.S)	nt Name PROFEN - UNII:WK2) Ingredient Na	ame 5856J3G2A2)		-	200 mg
IBUPROFEN (UNII: WK2) Inactive Ingredie STARCH, CORN (UNII: (POVIDONE K30 (UNII: (STEARIC ACID (UNII: 4E SILICON DIOXIDE (UNII SODIUM STARCH GLY(HYPROMELLOSE 2208	Ingredie XYI10QM) (IBUR ents D8232NY3SJ) U725QWY32X) ELV7Z65AP) I: ETJ7Z6XBU4) COLATE TYPE B (100 MPA.S) C3X673)	nt Name PROFEN - UNII:WK22 Ingredient Na A POTATO (UNII: UNII: B1QE5P712	ame 5856J3G2A2)		-	200 mg
IBUPROFEN (UNII: WK2) Inactive Ingredie STARCH, CORN (UNII: (POVIDONE K30 (UNII: (STEARIC ACID (UNII: 4E SILICON DIOXIDE (UNII SODIUM STARCH GLY0 HYPROMELLOSE 2208 TRIACETIN (UNII: XHX30	Ingredie XYI10QM) (IBUF ents D8232NY3SJ) U725QWY32X) ELV7Z65AP) I: ETJ7Z6XBU4) COLATE TYPE 3 (100 MPA.S) C3X673) ATE (UNII: EWC	nt Name PROFEN - UNII:WK23 Ingredient Na A POTATO (UNII:) (UNII: B1QE5P712 Q57Q8I5X)	ame 5856J3G2A2)		-	200 mg
IBUPROFEN (UNII: WK2) Inactive Ingredie STARCH, CORN (UNII: C POVIDONE K30 (UNII: C STEARIC ACID (UNII: 4E SILICON DIOXIDE (UNII SODIUM STARCH GLYC HYPROMELLOSE 2208 TRIACETIN (UNII: XHX30 LACTOSE MONOHYDR	Ingredie XYI10QM) (IBUF Ents D8232NY3SJ) U725QWY32X) ELV7Z65AP) I: ETJ7Z6XBU4) COLATE TYPE B (100 MPA.S) C3X673) XATE (UNII: EWC NII: 15FIX9V2JP	nt Name PROFEN - UNII:WK23 Ingredient Na A POTATO (UNII: UNII: B1QE5P712 Q57Q8I5X)	ame 5856J3G2A2)		-	200 mg
IBUPROFEN (UNII: WK2) Inactive Ingredie STARCH, CORN (UNII: C POVIDONE K30 (UNII: C STEARIC ACID (UNII: 4E SILICON DIOXIDE (UNII SODIUM STARCH GLYC HYPROMELLOSE 2208 TRIACETIN (UNII: XHX30 LACTOSE MONOHYDR TITANIUM DIOXIDE (UI	Ingredie XYI10QM) (IBUF Ents D8232NY3SJ) U725QWY32X) ELV7Z 65AP) I: ETJ7Z 6XBU4) COLATE TYPE B (100 MPA.S) C3X673) XATE (UNII: EWA NII: 15FIX9V2JP NII: 1K09F3G67	nt Name PROFEN - UNII:WK23 Ingredient Na A POTATO (UNII: UNII: B1QE5P712 Q57Q8I5X) Y5)	ame 5856J3G2A2)		-	200 mg
IBUPROFEN (UNII: WK2) Inactive Ingredie STARCH, CORN (UNII: (POVIDONE K30 (UNII: (STEARIC ACID (UNII: 4E SILICON DIOXIDE (UNII SODIUM STARCH GLY0 HYPROMELLOSE 2208 TRIACETIN (UNII: XHX30 LACTOSE MONOHYDR TITANIUM DIOXIDE (UI FERRIC OXIDE RED (UI	Ingredie XYI10QM) (IBUF Ents D8232NY3SJ) U725QWY32X) ELV7Z65AP) I: ETJ7Z6XBU4) COLATE TYPE 3 (100 MPA.S) C3X673) ATE (UNII: EWA NII: 15FIX9V2JP NII: 1K09F3G67 PRATE (UNII: L>	nt Name PROFEN - UNII:WK23 Ingredient Na A POTATO (UNII: (UNII: B1QE5P712 Q57Q8I5X)) 25) (22YL083G)	ame 5856J3G2A2)		-	200 mg
IBUPROFEN (UNII: WK2) Inactive Ingredie STARCH, CORN (UNII: C POVIDONE K30 (UNII: C STEARIC ACID (UNII: 4E SILICON DIOXIDE (UNII SODIUM STARCH GLYC HYPROMELLOSE 2208 TRIACETIN (UNII: XHX3C LACTOSE MONOHYDR TITANIUM DIOXIDE (UI FERRIC OXIDE RED (UI DEXTROSE MONOHYD	Ingredie XYI10QM) (IBUF ENTS 28232NY3SJ) U725QWY32X) ELV7Z65AP) I: ETJ7Z6XBU4) COLATE TYPE 3 (100 MPA.S) C3X673) EATE (UNII: EW NII: 15FIX9V2JP NII: 15FIX9V2JP NII: 15FIX9V2JP NII: 110156QDM	nt Name PROFEN - UNII:WK23 Ingredient Na A POTATO (UNII: (UNII: B1QE5P712 Q57Q8I5X)) 25) (22YL083G)	ame 5856J3G2A2)		-	200 mg

Product Characteristics					
Color	red	Score	no score		
Shape	OVAL (caplet)	Size	14mm		
Flavor		Imprint Code	G;2		
Contains					

Packaging						
#	ltem Code	Package Description	Marketing	g Start Date	Marke	ting End Date
1	NDC:62207-366-24	48000 in 1 BOX	01/01/2011			
2	NDC:62207-366-25	71000 in 1 BOX	01/01/2011			
3	NDC:62207-366-26	80000 in 1 BOX	01/01/2011			
4	NDC:62207-366-27	97000 in 1 BOX	01/01/2011			
5	NDC:62207-366-66	258000 in 1 DRUM	01/01/2011			
6	NDC:62207-366-67	190476 in 1 DRUM	01/01/2011			
7	NDC:62207-366-80	258000 in 1 DRUM	01/01/2011			
8	NDC:62207-366-68	175000 in 1 BOX	01/01/2011			
Marketing Information						
	Marketing Category	Application Number or M Citation	lonograph	Marketing S Date	tart	Marketing End Date
Ex	port only			01/01/2011		

Labeler - Granules India Limited (915000087)

Registrant - Granules India Limited (915000087)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Limited		918609236	manufacture(62207-365, 62207-366)

Revised: 12/2023

Granules India Limited