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 ■ 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

■ 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 years and older	■ take a caplet every 4 to 6 hours while 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 20-25ºC (68-77ºF)

■ 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.	**: 3650348A**	**No. of Units**	**: 2,58,899 (80 kg approx.)**
Mfg. Dt.	**: 10/2019**	**Gross Wt.**	**: 90.210 kg**
Exp. Dt.	**: 09/2022**	**Tare Wt.**	**: 10.210 kg**
NDC No.	**: 62207-365-16**	**Net Wet.**	**: 80.000 kg**
Mfg.Lic.No.	**: 37/RR/AP/2003/F/R**	**Container No**	**: 001**

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

Caution : For repacking only.

FOR TRANSPORTATION STUDY

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: xxxxxxxxxxx

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 - 25ºC (68 - 77ºF).
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,
Telangana, INDIA

Product code : F1179D7N

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

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

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,
Telangana, INDIA

Product code : F1180D7N

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

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

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,
Telangana, INDIA

Product code : F1079D3R

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

Country of Origin: INDIA

(00)18903832000000004

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 : F1079D3R

IBUPROFEN TABLETS, USP 200 mg (CAPLET)

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

Batch No. : XXXXXXX **No. of Tablets : 175,000 Tablets**

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

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,
Telangana, INDIA

Product code : F1076D3R

IBUPROFEN TABLETS, USP 200 mg (CAPLET)

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. : 62207-366-68 **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

Country of Origin: INDIA

(00)18903832000000004

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

IBUPROFEN

ibuprofen tablet

Product Information

Product Type	BULK INGREDIENT	**Item Code (Source)**	NDC:62207-365
Route of Administration	NOT APPLICABLE		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
TRIACETIN (UNII: XHX3C3X673)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	

Product Characteristics

Color	red	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	G;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-365-24	48000 in 1 BOX	01/01/2011	
2	NDC:62207-365-25	71000 in 1 BOX	01/01/2011	
3	NDC:62207-365-26	80000 in 1 BOX	01/01/2011	
4	NDC:62207-365-27	97000 in 1 BOX	01/01/2011	
5	NDC:62207-365-66	258000 in 1 DRUM	01/01/2011	
6	NDC:62207-365-67	190476 in 1 DRUM	01/01/2011	
7	NDC:62207-365-80	258000 in 1 DRUM	01/01/2011	

8	NDC:62207-365-68	175000 in 1 BOX	01/01/2011	
9	NDC:62207-365-16	258899 in 1 DRUM	11/10/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		01/01/2011	

IBUPROFEN

ibuprofen tablet

Product Information

Product Type	BULK INGREDIENT	**Item Code (Source)**	NDC:62207-366
Route of Administration	NOT APPLICABLE		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
TRIACETIN (UNII: XHX3C3X673)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing 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 Monograph Citation	Marketing Start Date	Marketing End Date
Export 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