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

■ 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

■ 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

■ 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**

adults and children 12 years and older	• 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

Front Side

NDC 62207-321-46

†Compare to the Active Ingredient of Motrin®IB

See New Warnings Information

Ibuprofen Tablets, USP

200 mg

Pain Reliever / Fever Reducer (NSAID)*

Do not use if foil inner seal is broken or missing.

Important: Read all product information before using. Keep the box for important information.

Contains no ingredient made from a gluten-containing grain (wheat, barley or rye).

***250** Coated Caplets†*
†Capsule-Shaped Tablets

Drug Facts

Active ingredient (in each caplet) — **Purposes**

Ibuprofen 200 mg ... (NSAID)* — 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

Drug Facts (continued)

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 chances is higher if you: ■ are age 60 or older ■ have had

Manufactured By:
Granules India Limited
Hyderabad – 500 043, India
MADE IN INDIA

Distributed By:
Granules USA, Inc.
Parsippany, NJ 07054

37/RIA/P/2003/FR
20000000XXXX

N 3 62207 32146 4

LOT:

EXP:

PEEL HERE

120 x 42 mm

1st Layer Adhesive Side

Drug Facts (continued)

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

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 ■ 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 ■ 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 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

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 ■ 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

2nd Layer

Drug Facts (continued)

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

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 caplets 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, polyethylene glycol, polyvinyl alcohol, povidone k30, 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

†This product is not manufactured or distributed by McNeil Consumer Healthcare Division, the owner of the registered trademark Motrin®IB

Drug Facts (continued)

■ 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 than10 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**

adults and children 12 years and older	• take 1 caplet every 4 to 6 hours while symptoms persist • If pain or fever does not respond to 1 caplet, 2 caplets may be used • do not exceed 6 caplets in 24 hours, unless directed by a doctor.
children under 12 years	• ask a doctor

See New Warnings Information

Ibuprofen Tablets USP, 200 mg

*Pain Reliever / Fever Reducer (NSAID)**

Contains no ingredient made from a gluten-containing grain (wheat, barley or rye).

250 Coated Caplets*
*Capsule-Shaped Tablets

*Compare to the Active Ingredient of Motrin®IB

NDC 62207-321-46

Important: Read all product information before using. Keep this box for important information.

Drug Facts

Active ingredient (in each caplet)	Purposes
Ibuprofen 200 mg (NSAID)*	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 chances 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]

Drug Facts (continued)

■ 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 ■ 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 ■ 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 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

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

Drug Facts (continued)

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, polyethylene glycol, polyvinyl alcohol, povidone, shellac glaze, simethicone emulsion, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments?
Call 1-877-776-3183
weekdays 8:00 AM to 4:30 PM EST

60 X 60 X 100

Manufactured By:
Granules India Limited
Hyderabad – 500 043. India.
MADE IN INDIA

Distributed By:
Granules USA, Inc.
Parsippany, NJ 07054

M.L. 370PAP/P/2009/FR

LOT:
EXP:

NDC 62207-320-46

See New Warnings Information

Ibuprofen Tablets USP, 200 mg

Pain Reliever / Fever Reducer (NSAID)*

Contains no ingredient made from a gluten-containing grain (wheat, barley or rye).

250 Coated Tables

§Compare to the Active Ingredient of Motrin®IB

Important: Read all product information before using. Keep this box for important information.

Drug Facts

Active ingredient (in each tablet)	***Purposes***
Ibuprofen 200 mg (NSAID)*	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

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This product contains an NSAID, which may cause severe stomach bleeding. The chances 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]

Drug Facts (contiuned)

■ 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 ■ 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 ■ 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 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

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

Drug Facts (contiuned)

■ 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 than10 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**

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

Drug Facts (contiuned)

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, polyethylene glycol, polyvinyl alcohol, povidone k30, 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

60 x 60 x 100

§This product is not manufactured or distributed by McNeil Consumer Healthcare Division, the owner of the registered trademark Motrin®IB

Manufactured By:
Granules India Limited
Hyderabad – 500 043, India
MADE IN INDIA

Distributed By:
Granules USA, Inc.
Parsippany, NJ 07054

M.L.: 37/RA/AP/2003/F/R

LOT:
EXP:

Front Side

NDC 62207-320-46

†Compare to the Active Ingredient of Motrin®IB

See New Warnings Information

Ibuprofen Tablets, USP

200 mg

Pain Reliever / Fever Reducer (NSAID)*

Do not use if foil inner seal is broken or missing.

Important: Read all product information before using. Keep the box for important information.

Contains no ingredient made from a gluten-containing grain (wheat, barley or rye).

250 Coated Tablets

Drug Facts

Active ingredient (in each tablet) — ***Purposes***

Ibuprofen 200 mg ... Pain reliever/fever reducer (NSAID)*

*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

Drug Facts (continued)

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

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Manufactured By:
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Hyderabad – 500 043, India
MADE IN INDIA

Distributed By:
Granules USA, Inc.
Parsippany, NJ 07054

37/RR/AP/2003/F/R
20000000XXXX

LOT:

EXP:

PEEL HERE

120 x 42 mm

1st Layer Adhesive Side

Drug Facts (continued)

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

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2nd Layer

Drug Facts (continued)

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**

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

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, polyethylene glycol, polyvinyl alcohol, povidone k30, 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

†This product is not manufactured or distributed by McNeil Consumer Healthcare Division, the owner of the registered trademark Motrin®IB

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
NDC No.	: 62207-321-91	Net Wt.	: 00.000 Kg
Mfg.Lic.No.	: 37/RR/AP/2003/F/R	Drum number	: 000

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

Caution : For repacking only.

Country of Origin: INDIA

(00)18903832000000004

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

Product code : 700000001995

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 Kg
Exp.Dt.	: MM/YYYY	Tare Wt.	: 00.000 Kg
NDC No.	: 62207-320-91	Net Wt.	: 00.000 Kg
Mfg.Lic.No.	: 37/RR/AP/2003/F/R	Drum number	: 000

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

Caution : For repacking only.

Country of Origin: INDIA

(00)18903832000000004

(01)50362207320912(17)000000(10)XXXXXXX

Product code : 700000001994

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	**Item Code (Source)**	NDC:62207-320
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
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			

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

IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62207-321
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

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
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

#	Item 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	

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)