

IBUPROFEN- ibuprofen tablet
Granules India Limited

Ibuprofen Tablets, 200 mg

ACTIVE INGREDIENT(S)

Ibuprofen 200mg (NSAID*)

*nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever / fever reducer

USE(S)

• 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 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)
- 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, or 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 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 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	<ul style="list-style-type: none">• take 1 tablet/caplet every 4 to 6 hours while symptoms persist.• if pain or fever does not respond to 1 tablet/caplet, 2 tablets/caplets may be used.• do not exceed 6 tablets/caplets in 24 hours, unless directed by a doctor.
children under 12 years	<ul style="list-style-type: none">• ask a doctor

OTHER INFORMATION

- store between 20° to 25°C (68° to 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

PRINCIPAL DISPLAY PANEL

Front Side

See New Warnings Information

Compare to the Active Ingredient in ibuprofen

NDC 62207-357-42

Ibuprofen Tablets, USP

200 mg

Pain Reliever / Fever Reducer (NSAID)*

50 Coated Tablets

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

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

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

Active ingredient Purpose (in each tablet)

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:

Allergy alert: Ibuprofen may cause

Drug Facts (continued)

a severe allergic reaction, especially in people allergic to aspirin.

Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin redness
- 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 are higher if



MADE IN INDIA

Manufactured By:
Granules India Limited
Hyderabad - 500 081,
INDIA

2000000000000
M.L. 27/05/16/2008/18



120 x 42 mm

1st Layer Adhesive Side

Drug Facts (continued)

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 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 problems, 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 during the last 3 months of pregnancy unless definitely decided 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. (1-800-622-1222)

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, polyvinylpyrrolidone 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 not manufactured or distributed by Akal. Consumer Health Division, a division of the registered trademark, MTR'S



¹Compare to the Active Ingredient of Motrin[®] IB
NDC 62207-357-49

See New Warnings Information

Ibuprofen Tablets, USP

200 mg

Pain Reliever / Fever Reducer (NSAID)²

1000 Coated Tablets

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

Important: Read all product information before using.

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



Drug Facts

Active ingredient (in each tablet) Ibuprofen, 200 mg (NSAID)¹..... Pain reliever/fever reducer

Purpose 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 redness
- 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 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

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

¹This product is not manufactured or distributed by McNeil Consumer Healthcare Division, the owner of the registered trademark Motrin[®] IB



MADE IN INDIA

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

Manufactured By:
Granules India Limited
Hyderabad - 500 081, INDIA
20000000000000

LOT:
EXP:



164 x 64 mm

Drug Facts (continued)

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:
 - feeling 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 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 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, polyvinylpyrrolidone 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

Ibuprofen Tablets USP 200mg (Caplet)

Each film coated tablet contains:

Ibuprofen USP 200 mg

Batch No. : XXXXXXX

Mfg.Dt. : MM/YYYY

Exp.Dt. : MM/YYYY

NDC No. : 62207-358-91

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

No. of Units : 160,000

Gross Wt. : 00.000 Kg

Tare Wt. : 00.000 Kg

Net Wt. : 00.000 Kg

Drum number : 000

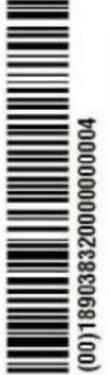
Storage : Store between 20 – 25 °C (68 – 77°F)

Caution : For repacking only.



(01)50362207358915(17)000000(10)XXXXXX

Country of Origin: INDIA



(00)189038320000000004

Product code : 70000001674

Activate
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Compare to the Active Ingredient of Motrin® B
NDC 62207-358-49

See New Warnings Information

Ibuprofen Tablets, USP

200 mg

Pain Reliever / Fever Reducer (NSAID)*

1000 Coated Caplets†
Capsule-Shape Tablets

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

Important: Read all product information before using.

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



Drug Facts

Purpose
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 redness ■ 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

*This product is not manufactured or distributed by Motrin Consumer Healthcare Division, the owner of the registered trademark Motrin® B



MADE IN INDIA

M. L. No.: 37/RR/AP/2003/RR

Manufactured By:
Granules India Limited
Hyderabad - 500 081, INDIA
200000900000

LOT:
EXP:



164 x 64 mm

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are
 taking aspirin for heart attack or stroke, because ibuprofen may decrease the 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 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 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**
- take 1 caplet every 4 to 6 hours while symptoms persist
- 12 years and older:**
- 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

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, poly(vinyl alcohol), polydextrose, pregelatinized starch, sodium starch glycolate, stearic acid, tac, titanium dioxide

Questions or comments?

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

Front Side



Compare to the Active Ingredient (ibuprofen)

See New Warnings Information

NDC 62207-358-42

Ibuprofen Tablets, USP

200 mg

Pain Reliever / Fever Reducer (NSAID)¹

50 Coated Caplets¹

¹Caplets Shaped Tablets

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).

Active Ingredient Purpose (in each caplet)
 Ibuprofen 200mg, 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

Drug Facts (continued)

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



MADE IN INDIA
 Manufactured By:
Granules India Limited
 Hyderabad - 500 081,
 INDIA

LOT:
 EXP:



120 x 42 mm

1st Layer Adhesive Side

Drug Facts (continued)

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 problems, 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 the 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 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 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

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 Nestlé Consumer Healthcare Division, the owner of the registered trademark Motrin®.

Ibuprofen Tablets USP 200 mg

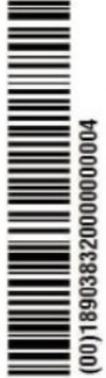
Each film coated tablet contains:

Ibuprofen USP 200 mg

Batch No. : XXXXXXXX
Mfg.Dt. : MM/YYYY
Exp.Dt. : MM/YYYY
NDC No. : 62207-357-91
Mfg.Lic.No. : 37/RR/AP/2003/F/R

No. of Units : 160,000
Gross Wt. : 00.000 Kg
Tare Wt. : 00.000 Kg
Net Wt. : 00.000 Kg
Drum number : 000

Country of Origin: INDIA



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

Caution : For repacking only.



(01)50362207357918(17)000000(10)XXXXXX

Product code : 700000001675

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Go to S

IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-357
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
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	G;3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-357-41	24 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2016	
2	NDC:62207-357-42	50 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2016	
3	NDC:62207-357-43	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2016	
4	NDC:62207-357-46	250 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2016	
5	NDC:62207-357-47	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2016	
6	NDC:62207-357-48	750 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2016	
7	NDC:62207-357-49	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2016	
8	NDC:62207-357-91	160000 in 1 DRUM	10/08/2018	
8		1 in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202312	11/17/2016	

IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-358
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
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

TALC (UNII: 7SEV7J4R1U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	Score	no score
Shape	OVAL	Size	14mm
Flavor		Imprint Code	G;3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-358-41	24 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2016	
2	NDC:62207-358-42	50 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2016	
3	NDC:62207-358-43	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2016	
4	NDC:62207-358-46	250 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2016	
5	NDC:62207-358-47	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2016	
6	NDC:62207-358-48	750 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2016	
7	NDC:62207-358-49	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2016	
8	NDC:62207-358-91	160000 in 1 DRUM	11/17/2016	
8		1 in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202312	11/17/2016	

Labeler - Granules India Limited (915000087)

Registrant - Granules India Limited (915000087)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Ltd		918609236	manufacture(62207-357, 62207-358) , label(62207-357, 62207-358)