# IBUPROFEN- ibuprofen tablet Granules India Limited

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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:

**l**headache

Imuscular aches

Ominor pain of arthritis

**Itoothache** 

**Dackache** 

Ithe common cold

Imenstrual 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	• take 1 tablet/caplet every 4 to 6 hours while		
children	symptoms persist.		
	<ul> <li>if pain or fever does not respond to</li> </ul>		
older	1 tablet/caplet, 2 tablets/caplets may be		
	used.		
	<ul> <li>do not exceed 6 tablets/caplets in 24 hours,</li> </ul>		
	unless directed by a doctor.		
children under	• ask a doctor		
12 years			

# 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

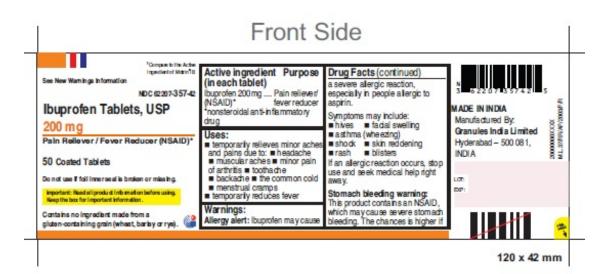
# **INACTIVE INGREDIENTS**

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



# 1st Layer Adhesive Side

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Do not use at you have ever had an eleging reaction to longer than directed or for longer than directed.

Do not use at you have ever had an allenge reaction to longer than directed or for longer than directed.

Do not use at you have problems, such he had at surgery.

Ask a doctor before use if a you have problems or shown as the earthorn a you have high lood pressure, heart disease, liver dirhosis.

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Stop use and sak a doctor if in you have symptoms of section or discussing thems. Stop use symptoms of heart problems or after.

- chest pain to discuss flower is also or less more than or negative or side or less more experience or less more than or negative or discussion or less more experience.

# 2nd Layer

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\*Compare to the Active Ingredient of Motrin\*IB

NDC 62207-357-49

See New Warnings Information

# IbuprofenTablets, USP

200 mg

Pain Reliever / Fever Reducer (NSAID)

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)

lbuprofen 200 mg (NSAID)\*.....\*
\*nonsteroidal anti-inflammatory drug

Pain reliever/ fever reducer

lemporarly relieves minor aches and pains due to:

■ headache ■ muscular aches ■ minor pain of arthitis ■ toothache
■ backache ■ the common cold ■ menstrual cramps

temporarily reduces fever

Wamings:

Alke gy akert, louprofen may cause a severe alergic reaction, especially in people alergic to asprint.

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bleeding. The chances is higher if you: 

are age 60 or older:

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(anticoagulant) or steroid orug a take other drugs containing

(anticoagulant) or steroid orug a take other drugs containing

prescription or nonprescription NSAIDs (asprin, libuprofen, naproxen, or Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach

others) = have 3 or more alcoholic drinks every day while using this product = take more or for a longer time than directors as the Heart attack and stroke warming: NSAIDs, except asplint increase the risks of heart allack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

not use 8 Ask a doctor before use if

if you have ever had an allergic reaction to ibuprofen or any other relieverflever reducer = right before or after heart surgery

■ you have problems or serious side effects from taking pain relievers or lever reduces ■ the stormed bleeding warning applies to you ■ you have a history of stornach problems, such as heartburn ■ you have high blood pressure, heart desease, iver crimosis, kidney disease, astirma, or had a stoke ■ you are taking a diuretic LOT EXP

<sup>5</sup>This product is not manufactured or distribute 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: 





164 x 64 mm

Drug Facts (continued)

for heart affack or stroke, because ibuprofer may neffi of aspirin 
under a doctor's care for any Ask a doctor or pharmacist before use if you are serious condition taking any other drug

Stop use and ask a doctor if a you experience any of the ood or milk if stomach upset occurs When using this product at take with food or milk if s

Idlowing signs of stornach bleeding - keelfant • vornit blood 
-have bloody or black stooks • have stornach pain had deesnot get 
better = you have symptoms of heart problems or stroke. 
• chest pain • trouble breathing • weakness in one part or side of body 
• shured speed • legs writing = paint gets wrose or fists more than 
10 days = lever gets worse or lasts more than 3 days = rethress or 
swelling is present in the painful area = any new symptoms

If pregnant or breast-feeding, ask a health professional before use. It is especially imporant not to see burporend multiple last 3 anouths of pregnancy unless definitely directed to do so by a dood or 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. (1-800-222-1)

 do not take more than directed Directions

 take 1 tablet every 4 to 6 hours while adults and children 12 years and older:

the smallest effective dose should be used

• if pain or lever does not respond to 1 tablet, 2 tablets may be used • do not exceed 6 tablets in 24 hours, unless symptoms persist

directed by a doctor · ask a doctor children under

Other Information:

 do not use if neck wrap or foil inner seal is broken or missing store between 20 – 25°C (68 – 77°F). Inactive ingredients

glycol, polyviny lalcohol, povidone k30, pregelatnized starch, sodium colloidal silicon dioxide, FD&C Yellow #6, maize starch, polyeth starch glycotate, stearicacid, talc, titanium dioxide

7-770-3183 weekdays 9:00 AM to 4:30 PM EST Questions or comments?

# **Ibuprofen Tablets USP 200mg (Caplet)**

No. of Units

Gross Wt.

Tare Wt.

Net Wt.

Drum number: 000

: 160,000

: 00.000 Kg

: 00.000 Kg

: 00.000 Kg

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

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

Caution: For repacking only.



(01)50362207358915(17)000000(10)XXXXXXX

Country of Origin: INDIA

Proposition of the State of the Settle Settl



Compare to the Active ingredient of Motin<sup>®</sup>B

NDC 62207-358-49

See New Warnings Information

# IbuprofenTablets, USP

# 200 mg

Pain Reliever / Fever Reducer (NSAID)\*

1000 Coated Caplets Capsule-Shaped 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).

# Pain relievent fever reducer

Active ingredient (in each caplet)
Iburoten 200 mg (NSAID)\*\*
\*nonsteroldsl anti-inflammatory drug **Drug Facts** 

 \*\*Memporarity relieves minor aches and pains due to:
 \*\*Peakdore in muscular aches in minor pain of arthritis in toothache
 \*\*Deckache in the common cold in mensitual gramps
 \*\*Remporarity reduces ferer Uses:

Warnings:

Allergy alert: buporden may cause a severe alergic reaction, especially in

Allergy alert: buporden may cause a severe alergic reaction, especially in

Symptoms may include: newell newelling mashing (Meecring)

ne shock a risk in reddening mash in biblions if an alergic reaction occurs, stop
use and seek medical help right away.

Stomech bleeding warming:
The product contains an NSAID, which may cause severe stomech
bleeding. The chances is higher if you: a see age 60 or older a have had
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product a take more of the allonger time than directed.
Heart takes and actickle warming: NSAIDs, except aspirin increase the
fisk of heart data. An at fallure, 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 even had an alergic reaction to ibuprofen or any other pain 
relievent ever reducer. In right before or after heart surgery

Ask a doctor before use if you sate effects from taking pain relevers or you have professers or senfous sate effects from taking pain relevers or fever reducers # the stormach bedong warning applies to you. # you have the history of stormach profesions, such as heartfurn # you have high blood pressure, heart disease, liver climosis, kidney disease, astirma, or had a storks # you are baking a duratic. LOT EXP

<sup>5</sup>This product is not manufactured or distribute by MoNeil Consumer Healthcare Division, the owner of the registered trademark Motrin\* B



MADE IN INDIA

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

Manufactured By: Granules India Limited Hyderabad - 500 081, INDIA 2000000000000



164 x 64 mm

Drug Facts (continued

Ask a doctor or pharmacist before use if you are

It skingagirin for heart affacts or stroke, because bupod enmay decrease this benefit of aspirin a under a doctor's carefor any serious condition a takingarry other drug When using this product

side with food or milkif si

lood or milk if stomach upset occurs

Stop use and ask a doctor if a you experience any of the following signs of stomach bleeding.\* heal faint\* vomitiood \* have bloody or bleck stooks \* have stomach pain heat does not get better a you have symptoms of heat procidents or stroke. • chest pain \* trouble breatting • weakness in one part or side of body string appeal gets worseo' is as more than 10 days a fever gets worseo it asts more than 3 days a rechessor swelling is present in the painful area a any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use, it is especially important not to use lupprofession during the last 3 months of pregnancy unless definitely directed to do so by a do do to because it may cause problems in the unborn child or 1. get medical (1-800-222-1)

Keep out of reach of children. In case of overdose, net or contact a Poison Control Center right away. (\*)

do not take more than directed
 the smallest effective dogs should be used

caplet, 2 caplets may be used • do not exceed 6 caplets in 24 hours, unless take 1 caplet every 4 to 6 hours while symptoms pensist

If pain or fever does not respond to 1 directed by a doctor aska doctor adults and children 12 years and older: children under

Other Information: 12 years:

 store between 20 – 25°C (68 – 77°F). do not use if neckwrap or foll inner

Inactive ingredients

glycol, polyvinyl alcohol, povidonek30, pregelatinized starch, sodiu starch glycolate, ste aric acid, talc, titarium dioxide colloidal silicon dioxide, FD&C Yellow 46, maize starch, polyeth;

Questions or comments? Cal 1-877-770-3183 weekdays 9:00 AM to 4:30 PM

EST

# Front Side



Compare to the Act we

NDC 62207-358-42

# Ibuprofen Tablets, USP

# 200 ma

Pain Reliever / Fever Reducer (NSAID)\*

50 Conted Capie to 1 Capeule 6haped Tablets

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

Contains no ingredient made from a gluten-cantaining grain (wheat, barley of 179).

# Active ingredient Purpose Drug Facts (continued)

(in each caplet) Ibuprofen 200mg... .Pain reliever/ (NSAID)\* fever reducer nonsteroidal anti-inflammatory

## drug Uses:

- temporarily relieves minor ache and pains due to: he adache muscular aches minor pain
- of arthitis 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 SWBY.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chances is higher if



MADE IN INDIA

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



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120 x 42 mm

# 1st Layer Adhesive Side

Drug Facts (continued)
your a are age 80 or older a have had
stomath uters or nebeding problems a take
a blood thinningent breading for steroid
drug a take other drugs containing
prescription or nonprescription NSAIDs,
expirit, buppolen, reprosen, or others)
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longer time than drected
Heart attack and stroke warming NSAIDs,
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except assignin increase as the after or heart
amork, heart failure, and stroke. These can
be fatal. The risk is higher if you use more
than drected or for forger than drected
Do not use a if you have ever had an
allergic reaction to blorder use if a you have
pain reliever/rever reducer a right before or
star heart surgery
Ask a doctor before use if a you have
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a you have a history of stomach problems,
such as heartitum a you have high blood
pressure, heart deesa e. Iver offnosis,
when a sking a duretic

Ask a doctor or pharmacists before use if
you are a taking a quiretic
any serious condition a taking any other drug
when using this product if a you
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expetence any of the following signs of
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# 2nd Layer

than 3 days a redness or swelling is presen in the painful area a any new symptoms continued

professional before use. It is especially important not to use buryon and running 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 overdoes, get medical help or contact a Poisson Compot Center right away.

(1-800-222-1222) If pregnant or breast-feeding, ask a health

respond to 1 caplet, 2 caplets may be used + do not exceed 6 caplets in 24 hours, unless dreded by a doctor.

 aska dodor moder

store between 20 – 25°C (68 – 77°F).
do not use if next wrap or foil inner seal broken or missing.

Inactive ingredients
colloidal silicon dodda, FD&C Yellow 46,
maize starch, polyethytene glycol, polyvinyl
acond, polydone k30, pregettirized starch,
sodum starch glycolete, stearic acid, tab,
ttantumdoxde

more Healthcare Division, the owner of the right mix Mothrill B Call 1-877- 770-3183 weekdays 9:00 AM to 4:30 PM EST Questions or comments?

# **Ibuprofen Tablets USP 200 mg**

No. of Units

Drum number : 000

Gross Wt.

Tare Wt.

Net Wt.

: 160,000

: 00.000 Kg

: 00.000 Kg : 00.000 Kg

Each film coated tablet contains:

Ibuprofen USP 200 mg

Batch No. : XXXXXXX Mfg.Dt. : MM/YYYY

Exp.Dt. : MM/YYYY

NDC No. : 62207-357-91

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

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

Caution: For repacking only.



(01)50362207357918(17)000000(10)XXXXXXX

Country of Origin: INDIA

Option of 100000001675

# **IBUPROFEN**

ibuprofen tablet

Droc	luct	Info	ımaı	tion
Prni			41121	

Product Type HUMAN OTC DRUG Item Code (Source) NDC:62207-357

Route of Administration ORAL

**Active Ingredient/Active Moiety** 

PO VIDO NE K30 (UNII: U725QWY32X)

Ingredient Name Basis of Strength Strength

IBUPRO FEN (UNII: WK2XYI10 QM) (IBUPRO FEN - UNII: WK2XYI10 QM) IBUPRO FEN 200 mg

Inactive Ingredients			
Ingredient Name	Strength		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)			
TALC (UNII: 7SEV7J4R1U)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
STARCH, CORN (UNII: O8232NY3SJ)			
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)			

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

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

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:62207-357-41	24 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/20 16	
2	NDC:62207-357-42	50 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/20 16	
3	NDC:62207-357-43	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/20 16	
4	NDC:62207-357-46	250 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/20 16	
5	NDC:62207-357-47	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/20 16	
6	NDC:62207-357-48	750 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/20 16	
7	NDC:62207-357-49	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/20 16	
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		
IBUPRO FEN (UNII: WK2XYI10 QM) (IBUPRO FEN - UNII: WK2XYI10 QM)	IBUPROFEN	200 mg		

Inactive Ingredients	
Ingredient Name	Strength
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

TALC (UNII: 7SEV7J4R1U)

SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)

STARCH, CORN (UNII: 08232NY3SJ)

POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)

PO VIDONE K30 (UNII: U725QWY32X)

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)

STEARIC ACID (UNII: 4ELV7Z65AP)

TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)

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

Packaging									
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date					
1	NDC:62207-358-41	24 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/20 16						
2	NDC:62207-358-42	50 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/20 16						
3	NDC:62207-358-43	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/20 16						
4	NDC:62207-358-46	250 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/20 16						
5	NDC:62207-358-47	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/20 16						
6	NDC:62207-358-48	750 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/20 16						
7	NDC:62207-358-49	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/17/20 16						
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	11/17/20 16						

# 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)				

Revised: 2/2021 Granules India Limited