

RANITIDINE- ranitidine tablet
RANITIDINE COOL MINT- ranitidine tablet
Granules India Ltd

Ranitidine Tablets

ACTIVE INGREDIENT(S)

Ranitidine 150 mg

PURPOSE

Acid reducer

USE(S)

- relieves heartburn associated with acid indigestion and sour stomach
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages

WARNINGS

Allergy alert: Do not use if you are allergic to ranitidine or other acid reducers

DO NOT USE

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

ASK A DOCTOR BEFORE USE IF

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

□ kidney disease

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

STOP USE AND ASK DOCTOR IF

- your heartburn continues or worsens
- you need to take this product for more than 14 days

PREGNANCY/BREASTFEEDING

ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS

- adults and children 12 years and over:
 - to **relieve** symptoms, swallow 1 tablet with a glass of water
 - to **prevent** symptoms, swallow 1 tablet with a glass of water □
 - **30 to 60 minutes before** eating food or drinking beverages that cause heartburn
 - can be used up to twice daily (do not take more than 2 tablets in 24 hours)
 - do not chew tablet (for cool mint tablets only)
- children under 12 years: ask a doctor

OTHER INFORMATION

- do not use if individual blister unit is open or torn.
- do not use if printed foil under bottle cap is open or torn
- store at 20⁰-25⁰C (68⁰-77⁰F)
- avoid excessive heat or humidity
- this product is sodium and sugar free

INACTIVE INGREDIENTS

For 150 mg: croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talcum, titanium dioxide

For 150 mg cool mint: acacia, croscarmellose sodium, FD&C Blue No. 1, magnesium stearate, menthol, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talcum, titanium dioxide

Questions or comments?

•Contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM EST.

This product is not manufactured or distributed by Boehringer Ingelheim® consumer health care products, distributor of Zantac 150mg and 150mg Cool Mint

Read the directions and warnings before use.

Keep the carton. It contains important information including tips for managing heartburn.

Tips for managing heartburn

- Do not lie flat or bend over soon after eating

- Do not eat late at night, or just before bedtime

- Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol, even some fruits and vegetables.

- Eat slowly and do not eat big meals

- if you are overweight, lose weight

- if you smoke, quit smoking

- Raise the head of your bed

- Wear loose fitting clothing around your stomach

PRINCIPAL DISPLAY PANEL

Labeling Format Information	
Format	Description
Font Style	Helvetica Narrow, Bold, Italic
Drug Facts	10 pt
Drug Facts (continued)	9 pt
Header	7 pt
Body Text	6 pt
Bullet (solid square)	5 pt
Barline	2 pt
Headline	10.5 pt
Drug Title	15 pt
Justification	Left
Revision	02

Un varnish coding area

LOT: _____
EXP: _____

XXXXXXXXXXXX

Manufactured by:
Granules India Limited
Hyderabad - 500 081,
India
Manufactured by:
Granules USA, Inc.
Parapilly, NJ 07054
Toll Free: 1-877-770-9183

Read the directions and warnings before use. Keep the carton in a cool, dry place. Do not use if the seal is broken or the tablets are discolored.

NDC 62207-774-41

COOL MINT TABLETS
MAXIMUM STRENGTH
Ranitidine Tablets, USP
150 mg

Acid Reducer
PREVENTS & RELIEVES HEARTBURN
associated with acid indigestion
and sour stomach

**Releases a Cooling Sensation in
Mouth and Throat**

[†]Compare to the active ingredient of
Zantac 150 Cool Mint[®]

24 Tablets
(24 Doses)



Drug Facts

Active ingredient **Purpose**
(in each tablet)
Ranitidine 150 mg
(as ranitidine hydrochloride 168 mg). Acid reducer

Uses

- relieves heartburn associated with acid indigestion and sour stomach
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages

Warnings

Allergy alert: Do not use if you are allergic to ranitidine or other acid reducers

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight

Drug Facts (continued)

loss ■ nausea or vomiting ■ stomach pain
■ kidney disease

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days

If **pregnant or breast-feeding**, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years and over:
 - to **relieve symptoms**, swallow 1 tablet with a glass of water
 - to **prevent symptoms**, swallow 1 tablet with a glass of water **30 to 60 minutes before eating** food or drinking beverages that cause heartburn
 - can be used up to twice daily (do not take more than 2 tablets in 24 hours)
- do not chew tablet
- children under 12 years: ask a doctor

Other information

- do not use if printed foil under bottle cap is open or

Drug Facts (continued)

store at 20°-25°C (68°-77°F) ■ avoid excessive heat or humidity ■ this product is sodium and sugar free

Inactive ingredients
acacia, croscarmellose sodium, FD&C Blue No. 1, magnesium stearate, menthol, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talcum, titanium dioxide

Questions or comments?
Contact 1-877-770-9183
Mon-Fri 8:00 AM EST to 5:00 PM EST.

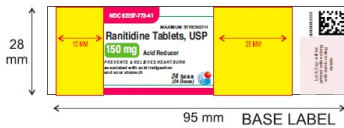
[†]This product is not manufactured or distributed by Boehringer Ingelheim consumer health care products, distributor of Zantac 150 Cool Mint[®]

Tips for managing heartburn

- Do not lie flat or bend over soon after eating
- Do not eat late at night, or just before bedtime
- Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol, even some fruits and vegetables.
- Eat slowly and do not eat big meals
- if you are overweight, lose weight
- if you smoke, quit smoking
- Raise the head of your bed
- Wear loose fitting clothing around your stomach

Labeling Format Information	
Format	Description
Font Style	Helvetica Narrow, Bold, Italic
Drug Facts	10 pt
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Bullet (solid square)	5 pt
Barline	2 pt
Hairline	0.5 pt
Drug Title	15 pt
Justification	Left
Revision	02

UNWINDING DIRECTION
←



- PRINTING AREA
FILL ALL TEXT AND GRAPHIC INSIDE GREEN AREA
- GLUE AREA
BLANK
- PAPER AREA

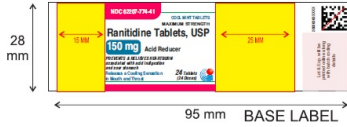
APP. DATE : 02-07-2015
UNICK FIX-A-FORM AND PRINTERS LTD.

IP part-1 FRONT

IP part-1 BACK

Labeling Format Information	
Format	Description
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Drug Facts (continued)	9 pt
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Hairline	0.5 pt
Drug Title	15 pt
Justification	Left
Revision	02

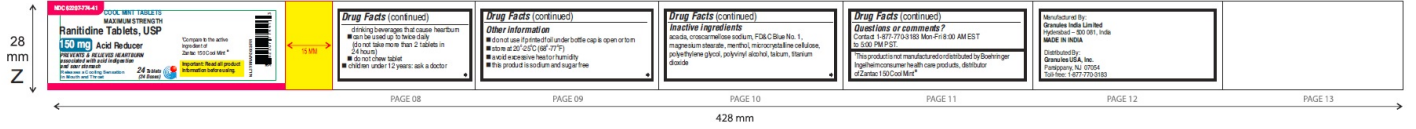
UNWINDING
DIRECTION



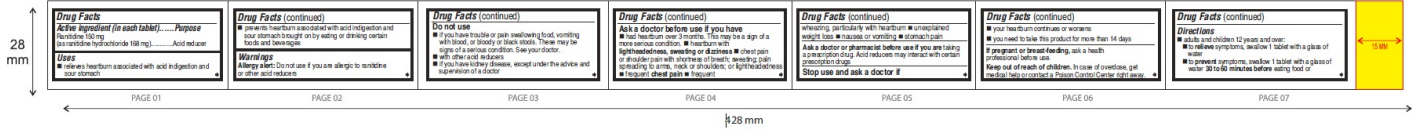
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FILL ALL TEXT AND GRAPHIC INSIDE
GREEN AREA
- GLUE AREA
BLANK
- PAPER AREA

APP. DATE : 02-07-2015
UNICK FIX-A-FORM AND PRINTERS LTD.

IP part-1 FRONT



IP part-1 BACK



Labeling Format Information	
Field	Barcode
Print Date	10/10/2015
Drug Name	Ranitidine Tablets, USP
Strength	150 mg
Quantity	30 Tablets
Form	Tablet
Lot No.	15071703193
Exp. Date	12/31/16
Manufacturer	Dr. Reddy's Laboratories
Country	INDIA
Barcode	81401015071703193

NDC 62207-774-47

COOL MINT TABLETS
MAXIMUM STRENGTH

Ranitidine Tablets, USP

150 mg

Acid Reducer

PREVENTS & RELIEVES HEARTBURN

associated with acid indigestion and
sour stomach

Releases a Cooling Sensation in
Mouth and Throat

500 Tablets
(500 Doses)

*Compare to the active ingredient of
Zantac 150 Cool Mint*



Important: Read all product information before using.

Drug Facts

Active ingredient (in each tablet),.....Purpose

Ranitidine 150 mg
(as ranitidine hydrochloride 168 mg).....Acid reducer

Uses

- relieves heartburn associated with acid indigestion and sour stomach
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages

Warnings

Allergy alert Do not use if you are allergic to ranitidine or other acid reducers

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers
- if you have kidney disease, except under the advice and supervision of a doctor

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with

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

Distributed By:
Granules USA, Inc.
Parsippany, NJ 07054
Toll-free: 1-877-770-3183



200 00000 XXXX

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

LOT:

EXP:

164 x 64 mm

Drug Facts (continued)

shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducer may interact with certain prescription drugs

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years and over:
 - to relieve symptoms, swallow 1 tablet with a glass of water
 - to prevent symptoms, swallow 1 tablet with a glass of water 30 to 60 minutes before eating food or drinking beverages that cause heartburn
- can be used up to twice daily (do not take more than 2 tablets in 24 hours)
- do not chew tablet
- children under 12 years: ask a doctor

Other information

- do not use if printed lot underbottle cap is open or torn
- store at 20°-25° C (68°-77° F) ■ avoid excessive heat or humidity
- this product is sodium and sugar free

Inactive ingredients

acacia, croscarmellose sodium, FD&C Blue No. 1, magnesium stearate, menthol, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talcum, titanium dioxide

Questions or comments?

Contact: 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST.
This product is not manufactured or distributed by Boehringer Ingelheim consumer health care products, distributor of Zantac 150 Cool Mint

164 x 64 mm

NDC 62207-773-47

MAXIMUM STRENGTH

Ranitidine Tablets, USP

150 mg

Acid Reducer

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

500 Tablets (500 Doses)

¹ Compare to the active ingredient of Zantac 150*



Important: Read all product information before using.

Drug Facts

Active ingredient (in each tablet):.....**Purpose**

Ranitidine 150 mg (as ranitidine hydrochloride 168 mg).....Acid reducer

Uses

- relieves heartburn associated with acid indigestion and sour stomach
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages

Warnings

Allergy alert: Do not use if you are allergic to ranitidine or other acid reducers

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers
- if you have kidney disease, except under the advice and supervision of a doctor

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with

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

Distributed By: Granules USA, Inc. Parsippany, NJ 07054 Toll-free: 1-877-770-3183



200000 00XXXX M.L. No.: 37/RR/AP/2003/FR

LOT: EXP:



164 x 64 mm

Drug Facts (continued)

shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducer may interact with certain prescription drugs

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years and over:
 - to relieve symptoms, swallow 1 tablet with a glass of water
 - to prevent symptoms, swallow 1 tablet with a glass of water 30 to 60 minutes before eating food or drinking beverages that cause heartburn
- can be used up to twice daily (do not take more than 2 tablets in 24 hours)
- children under 12 years: ask a doctor

Other information

- do not use if crimped foil under bottle cap is open or torn
- store at 20°-25°C (68°-77°F) ■ avoid excessive heat or humidity
- this product is sodium and sugar free

Inactive ingredients

croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talcum, titanium dioxide

Questions or comments?

Contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST.

This product is not manufactured or distributed by Boehringer Ingelheim consumer health care products, distributor of Zantac 150

RANITIDINE TABLETS, USP 150 mg Cool mint

Each film coated tablet contains

Ranitidine 150 mg

(as Ranitidine hydrochloride USP 168 mg)

Batch No. : XXXXXXXX

No. of Units : 10,000's

Mfg.Dt. : MM/YYYY

Exp.Dt. : MM/YYYY

NDC No. : 62207-774-32

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

Storage : Store at 20°-25°C (68°-77°F) Avoid excessive heat or humidity

Caution : For repacking only.

Country of Origin: INDIA

Product code : 70000001630

RANITIDINE TABLETS, USP 150 mg

Each film coated tablet contains:

Ranitidine 150 mg

(as Ranitidine hydrochloride USP 168 mg)

Batch No. : XXXXXXXX

No. of Units : 10,000's

Mfg.Dt. : MM/YYYY

Exp.Dt. : MM/YYYY

NDC No. : 62207-773-32

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

Storage : Store at 20°-25°C (68°-77°F) Avoid excessive heat or humidity

Caution : For repacking only.

Country of Origin: INDIA

Product code : 70000001629

RANITIDINE TABLETS, USP 150 mg Cool mint

Each film coated tablet contains

Ranitidine 150 mg

(as Ranitidine hydrochloride USP 168 mg)

Batch No. : XXXXXXX

No. of Units : 5x10,000's

Mfg.Dt. : MM/YYYY

Gross Wt. : 00.000 Kg

Exp.Dt. : MM/YYYY

Tare Wt. : 00.000 Kg

NDC No. : 62207-774-36

Net Wt. : 00.000 Kg

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

Box number : 000

Storage : Store at 20°-25°C (68°-77°F) Avoid excessive heat or humidity

Caution : For repacking only.



(01)50362207774364(17)000000(10)XXXXXXX

Country of Origin: INDIA



(00)189038320000000004

Product code : 700000001630

RANITIDINE TABLETS, USP 150 mg

Each film coated tablet contains

Ranitidine 150 mg

(as Ranitidine hydrochloride USP 168 mg)

Batch No. : XXXXXXX

No. of Units : 5x10,000's

Mfg.Dt. : MM/YYYY

Gross Wt. : 00.000 Kg

Exp.Dt. : MM/YYYY

Tare Wt. : 00.000 Kg

NDC No. : 62207-773-36

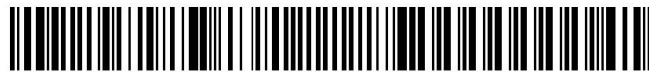
Net Wt. : 00.000 Kg

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

Box number : 000

Storage : Store at 20°-25°C (68°-77°F) Avoid excessive heat or humidity

Caution : For repacking only.



(01)50362207773367(17)000000(10)XXXXXXX

Country of Origin: INDIA



(00)189038320000000004

Product code : 700000001629

RANITIDINE

ranitidine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-773
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RANITIDINE HYDROCHLORIDE (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10YB7)	RANITIDINE	150 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	150;G
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-773-58	2 in 1 CARTON	06/26/2019	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:62207-773-41	1 in 1 CARTON	06/26/2019	
2		24 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:62207-773-47	1 in 1 CARTON	06/26/2019	
3		500 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:62207-773-36	5 in 1 CARTON	06/26/2019	
4	NDC:62207-773-32	10000 in 1 BAG; Type 0: Not a Combination Product		

RANITIDINE TABLETS, USP 150 mg

Each film coated tablet contains:

Ranitidine 150 mg

(as Ranitidine hydrochloride USP 168 mg)

Batch No. : XXXXXXXX

No. of Units : 10,000's

Mfg.Dt. : MM/YYYY

Exp.Dt. : MM/YYYY

NDC No. : 62207-773-32

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

Storage : Store at 20°-25°C (68°-77°F) Avoid excessive heat or humidity

Caution : For repacking only.

Country of Origin: INDIA

Product code : 700000001629

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210243	06/26/2019	

RANITIDINE COOL MINT

ranitidine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-774
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RANITIDINE HYDROCHLORIDE (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10YB7)	RANITIDINE	150 mg

Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	

FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
MAGNESIUM STEARATE (UNII: 70097M6I30)
MENTHOL (UNII: L7T10EP3A)
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)
POLYVINYL ALCOHOL (UNII: 532B59J990)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	blue	Score	no score
Shape	ROUND	Size	9mm
Flavor	MINT	Imprint Code	150;G
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-774-58	2 in 1 CARTON	06/26/2019	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:62207-774-41	1 in 1 CARTON	06/26/2019	
2		24 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:62207-774-47	1 in 1 CARTON	06/26/2019	
3		500 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:62207-774-36	5 in 1 CARTON	06/26/2019	
4		10000 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	ANDA210243	06/26/2019	

Labeler - Granules India Ltd (915000087)

Registrant - Granules India Ltd (918609236)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Ltd		918609236	manufacture(62207-773, 62207-774)