

**OMEPRAZOLE AND SODIUM BICARBONATE- omeprazole and sodium bicarbonate powder, for suspension
Dr. Reddy's Laboratories Inc.,**

Drug Facts

Active ingredient(s)

Drug Facts

Active ingredients

Purpose

(in each powder packet)

Omeprazole, USP 20 mg Acid reducer

Sodium Bicarbonate, USP 1,680 mg Allows absorption of this omeprazole product

Purpose

Acid reducer

Allows absorption of this omeprazole product

Use(s)

- treats frequent heartburn (occurs **2 or more** days a week)
- not intended for immediate relief of heartburn. This drug may take 1 to 4 days for full effect.

Warnings

Allergy alert:

- do not use if you are allergic to omeprazole
- omeprazole may cause severe skin reactions. Symptoms may include
- skin reddening
- blisters
- rash.

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- 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**

These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have:

- had heartburn over 3 months. This may be a sign of a more serious condition.
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain
- a sodium-restricted diet

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 unless directed by your doctor
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
- you develop a rash or joint pain

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 (1-800-222-1222).

Directions

- for adults 18 years of age and older:
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- product should be taken at least 1 hour before eating in the morning
- take every day for 14 days
- do not take more than once a day
- empty packet contents into a small cup containing 2 tablespoons of **WATER**
- DO NOT USE WITH OTHER LIQUIDS OR FOOD
- stir well and drink immediately
- refill cup with water and drink
- do not use for more than 14 days unless directed by your doctor

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months

- **do not take for more than 14 days or more often than every 4 months unless directed by a doctor**
- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information

- each powder packet contains: **sodium 460 mg**
- read the directions and warnings before use
- keep the carton. It contains important information
- store between 20° to 25 °C (68° to 77°F)
- tamper-evident: do not use if foil is open or broken
- keep product out of high heat and humidity
- protect product from moisture

Inactive ingredients

mixed berries flavor, sucralose, sucrose, xanthan gum, xylitol

and

menthol plus peppermint flavor, sucralose, sucrose, xanthan gum, xylitol

Questions or comments?

call toll-free weekdays 8 AM to 8 PM EST Call 1-888-375-3784

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 and 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

HOW OMEPRAZOLE AND SODIUM BICARBONATE POWDER FOR ORAL SUSPENSION WORKS FOR YOUR FREQUENT HEARTBURN

Omeprazole and Sodium Bicarbonate Powder for Oral Suspension works differently from other OTC heartburn products, such as antacids and other acid reducers.

Omeprazole and Sodium Bicarbonate Powder for Oral Suspension stops acid production at the source – the acid pump that produces stomach acid. Omeprazole and Sodium Bicarbonate Powder for Oral Suspension is to be used once a day (every 24 hours), every day for 14 days.

*This product is not manufactured or distributed by Santarus, Inc. or Riley Consumer Care. Zegerid OTC® is a registered trademark of Santarus, Inc.

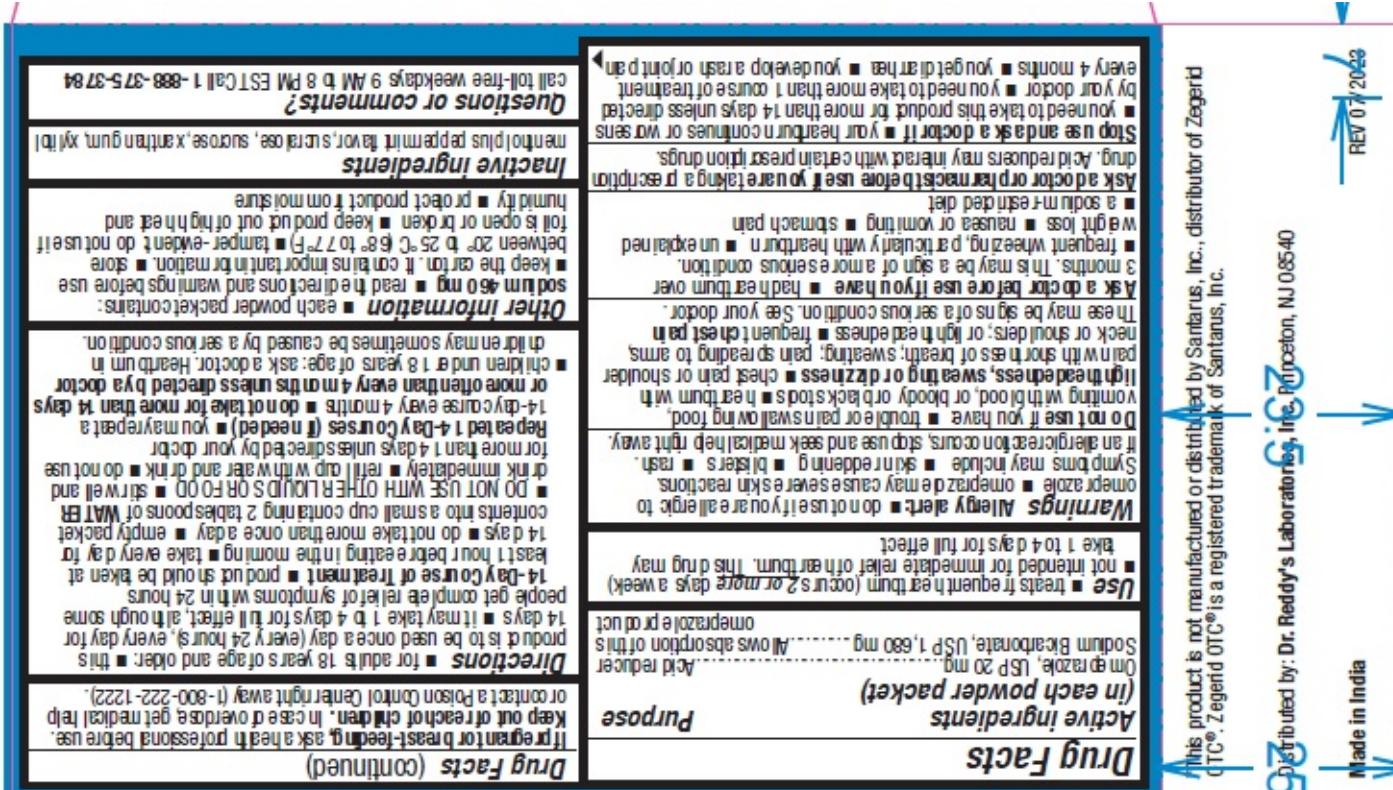
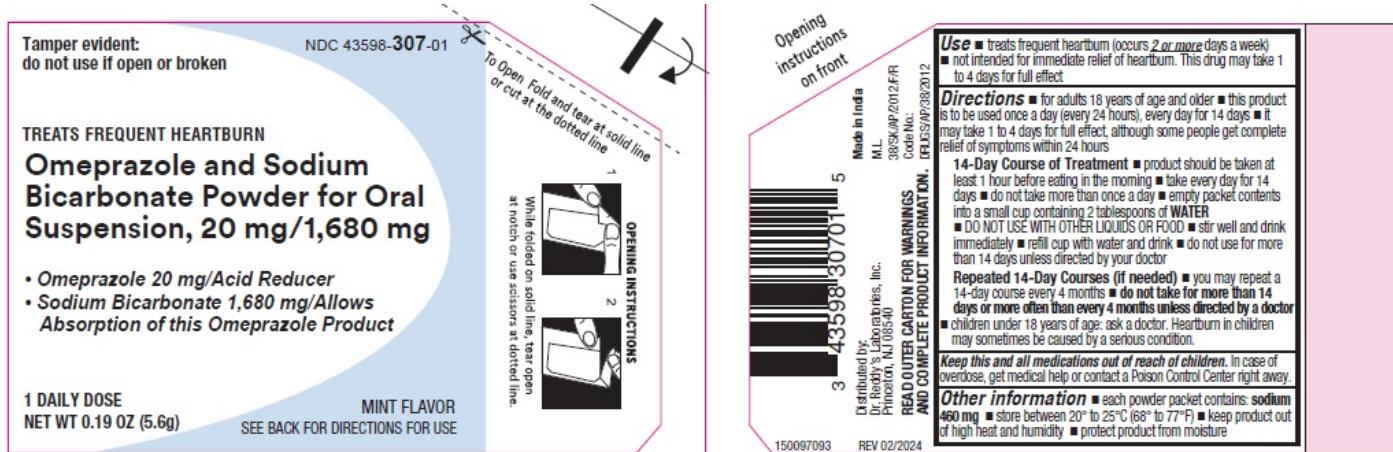
Distributed by:

Dr. Reddy's Laboratories, Inc.

Princeton, NJ 08540

Made in India

Issued: 07/2023



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18.5

25

295

This product is not manufactured or distributed by Santarus, Inc., distributor of Zegerid.



NDC 43598-307-01

MINT FLAVOR

TREATS FREQUENT HEARTBURN

**Compare to the active ingredients in
Zegerid OTC® Powder for Oral Suspension***

Omeprazole and Sodium Bicarbonate Powder for Oral Suspension 20 mg/1,680 mg

- **Omeprazole 20 mg/Acid Reducer**
- **Sodium Bicarbonate 1,680 mg/Allows Absorption of this Omeprazole Product**



NET WT 0.19 OZ (5.6g)

**1 POWDER PACKET
ONE DOSE OF A 14-DAY COURSE OF TREATMENT**

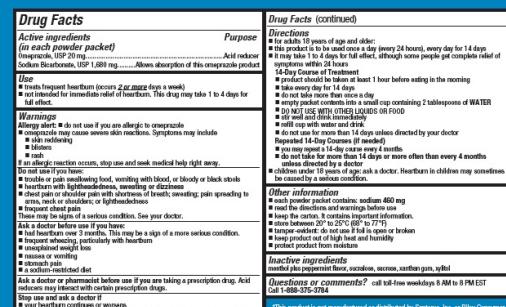
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HOW OMEPRAZOLE AND SODIUM BICARBONATE POWDER FOR ORAL SUSPENSION WORKS FOR YOUR FREQUENT HEARTBURN

Omeprazole and Sodium Bicarbonate Powder for Oral Suspension works differently from other OTC heartburn products, such as antacids and other acid reducers. **Omeprazole and Sodium Bicarbonate Powder for Oral Suspension** stops acid production at the source – the **acid pump** that produces stomach acid. **Omeprazole and Sodium Bicarbonate Powder for Oral Suspension** is to be used once a day (every 24 hours), every day for 14 days.

Omeprazole 20 mg /Acid Reducer

Sodium Bicarbonate 1,680 mg/Allows Absorption of this Omeprazole Product



TIPS FOR MANAGING HEARTBURN

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M.L. 38/ISK/AP/2012/F/R
Code No.: DRUGS/AP/38/2012



Omeprazole 20 mg /Acid Reducer

Sodium Bicarbonate 1,680 mg/Allows Absorption of this Omeprazole Product

Omeprazole 20 mg /Acid ReducerSodium Bicarbonate 1,680 mg/Allows Absorption of this Omeprazole Product

Tamper evident:
do not use if open or broken

NDC 43598-010-01

TREATS FREQUENT HEARTBURN

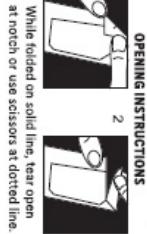
Omeprazole and Sodium Bicarbonate Powder for Oral Suspension, 20 mg/1,680 mg

- Omeprazole 20 mg/Acid Reducer
- Sodium Bicarbonate 1,680 mg/Allows Absorption of this Omeprazole Product

1 DAILY DOSE
NET WT 0.19 OZ (5.6g)

MIXED BERRIES FLAVOR
SEE BACK FOR DIRECTIONS FOR USE

To Open Fold and tear at solid line
or cut at the dotted line



Opening
instructions
on front

Use ■ treats frequent heartburn (occurs 2 or more days a week)
■ not intended for immediate relief of heartburn. This drug may take 1 to 4 days for full effect

Directions ■ for adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment ■ product should be taken at least 1 hour before eating in the morning ■ take every day for 14 days ■ do not take more than once a day ■ empty packet contents into a small cup containing 2 tablespoons of **WATER**
■ **DO NOT USE WITH OTHER LIQUIDS OR FOOD** ■ stir well and drink immediately ■ refill cup with water and drink ■ do not use for more than 14 days unless directed by your doctor

Repeated 14-Day Courses (if needed) ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor
■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition

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

Other information ■ each powder packet contains: sodium 460 mg ■ store between 20° to 25°C (68° to 77°F) ■ keep product out of high heat and humidity ■ protect product from moisture

Made in India
M.L.
389SKAP/2012/F.R
Code No.:
TFLG/549/28/2012

Distributed by:
Dr. Reddy's Laboratories, Inc.
Pinebrook, NJ 07054-40

**READ OUTER CARTON FOR WARNINGS
AND COMPLETE PRODUCT INFORMATION.** (TFLG/549/28/2012)

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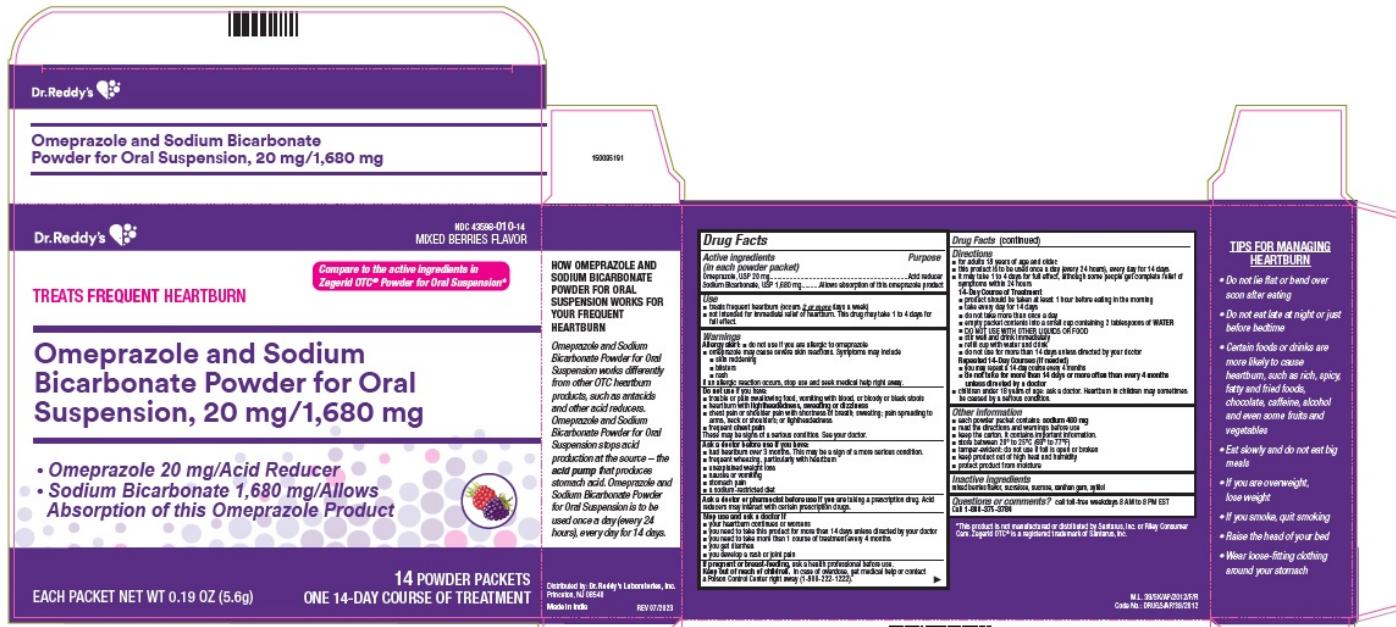
REV 02/2024



Principal Display Panel

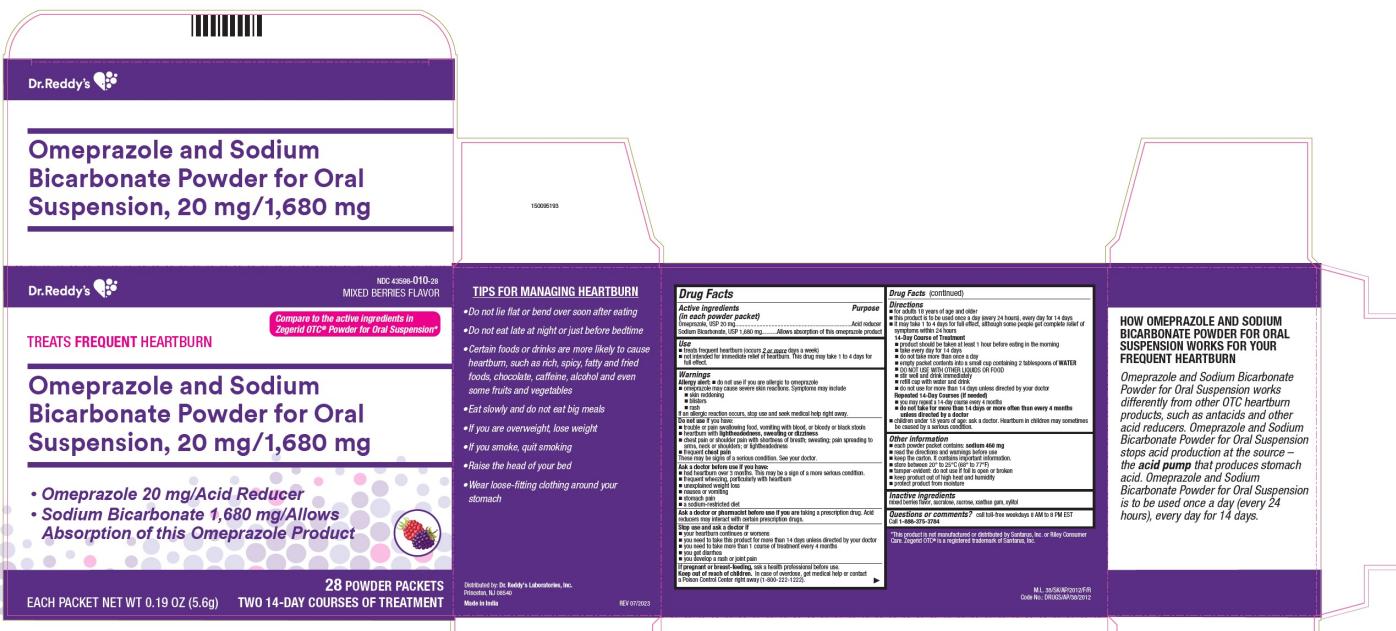
Omeprazole 20 mg /Acid Reducer

Sodium Bicarbonate 1,680 mg/Allows Absorption of this Omeprazole Product



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Sodium Bicarbonate 1,680 mg/Allows Absorption of this Omeprazole Product



OMEPRAZOLE AND SODIUM BICARBONATE

omeprazole and sodium bicarbonate powder, for suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43598-010
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20 mg
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	1680 mg

Inactive Ingredients

Ingredient Name	Strength
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43598-010-01	1 in 1 CARTON	07/15/2024	
1		1 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:43598-010-14	14 in 1 CARTON	07/15/2024	
2		1 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:43598-010-28	28 in 1 CARTON	07/15/2024	
3		1 in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:43598-010-42	42 in 1 CARTON	07/15/2024	
4		1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217784	07/15/2024	

OMEPRAZOLE AND SODIUM BICARBONATE

omeprazole and sodium bicarbonate powder, for suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43598-307
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20 mg
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	1680 mg

Inactive Ingredients

Ingredient Name	Strength
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT, PEPPERMINT	Imprint Code	
Contains			

Packaging

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3		1 in 1 PACKET; Type 0: Not a Combination Product		
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ANDA	ANDA217784	07/15/2024	

Labeler - Dr. Reddy's Laboratories Inc., (802315887)

Establishment

Name	Address	ID/FEI	Business Operations
Dr. Reddy's Laboratories Limited-PU-1		860037244	analysis(43598-010, 43598-307) , manufacture(43598-010, 43598-307) , pack(43598-010, 43598-307)

Establishment

Name	Address	ID/FEI	Business Operations
Quality Packaging Specialists International, LLC		825078165	pack(43598-010, 43598-307)

Revised: 7/2023

Dr. Reddy's Laboratories Inc.,