GUAIFENESIN- guaifenesin tablet, extended release
Ohm Laboratories, Inc.

Drug Facts

Active ingredient

(in each extended-release tablet)

Guaifenesin, USP

Purpose

Expectorant

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).

Uses

- Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bronchial mucus and make coughs more productive

Warnings

Do not use

- for children under 12 years of age

Ask a doctor before use if you have

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough accompanied by too much phlegm (mucus)

Stop use and ask a doctor if

- cough lasts more than 7 days, comes back or occurs with fever, rash, or persistent headache.
  These could be signs of serious illness.

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

Directions

- do not crush, chew or break extended-release tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children over 12 years of age and over: one or two extended-release tablets every 12 hours. Do not exceed 4 extended-release tablets in 24 hours.
- children under 12 years of age: do not use.

Other information

- store between 20-25°C (68-77°F)
- **TAMPER EVIDENT: DO NOT USE IF CARTON IS OPEN OR IF PRINTED SEAL ON BLISTER IS BROKEN OR MISSING.**

Keep the carton. It contains important information. See end panel for expiration date.

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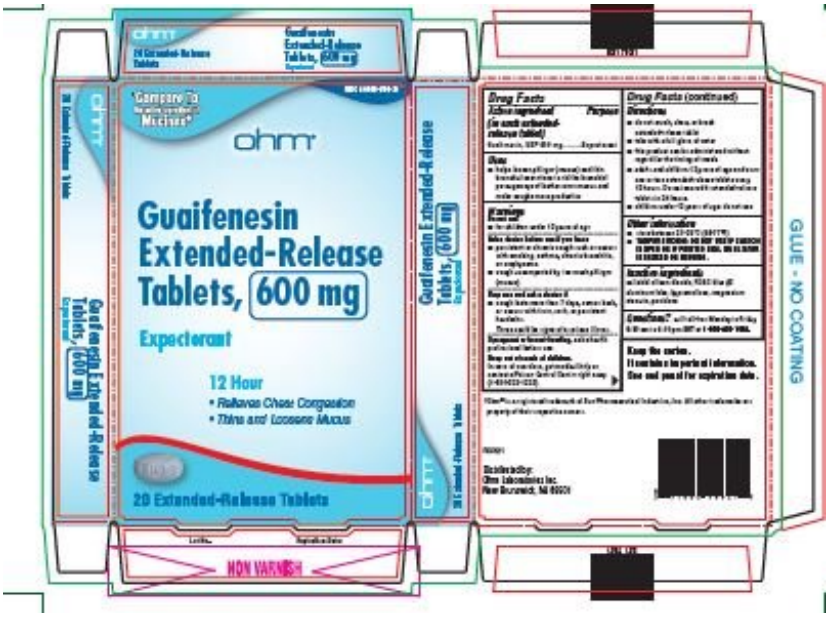
Inactive Ingredients

colloidal silicon dioxide, FD&C blue # 2, aluminum lake, hypromellose, magnesium stearate, povidone.

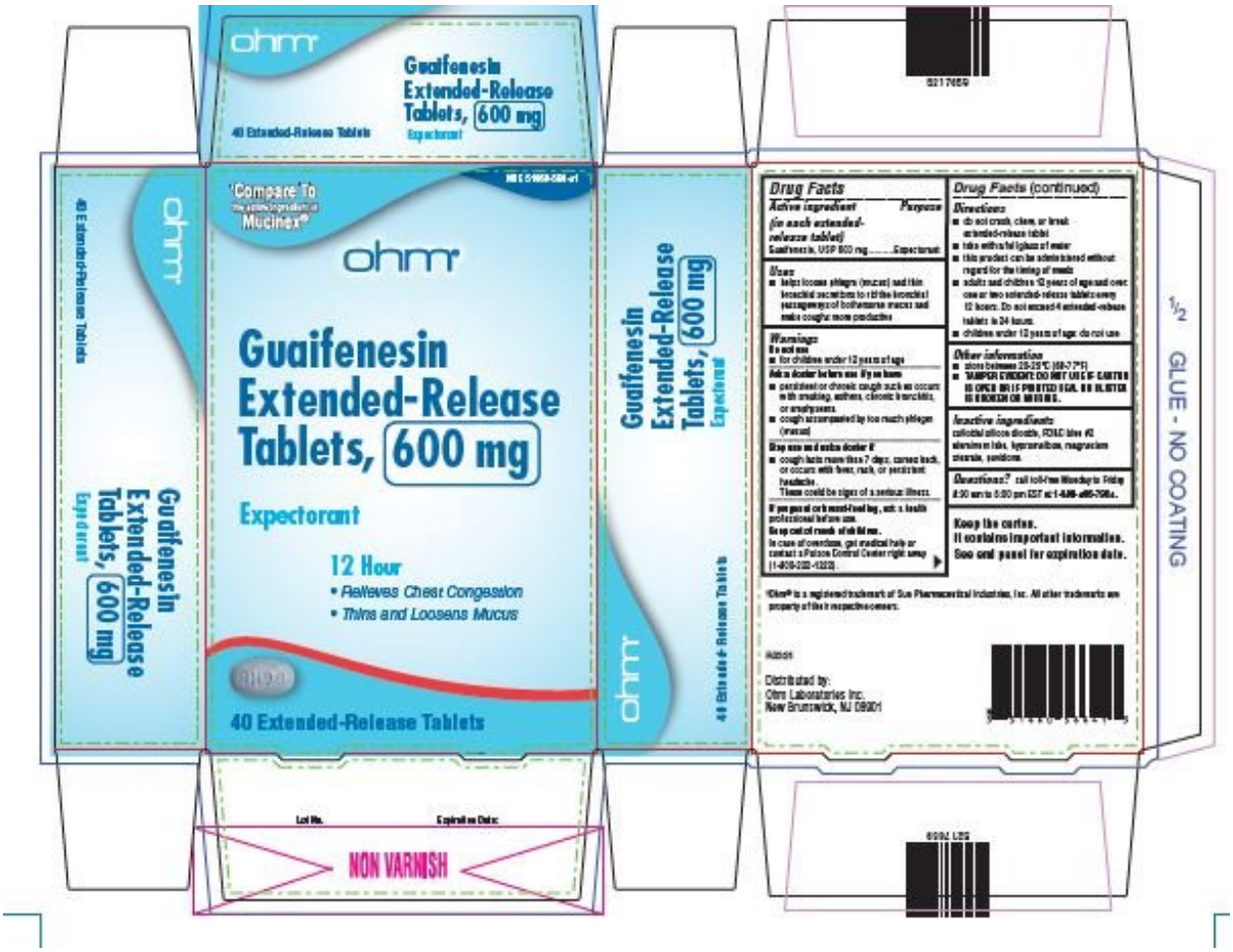
Questions

call toll-free Monday to Friday 8:30 am to 5:00 pm EST at 1-800-406-7984.

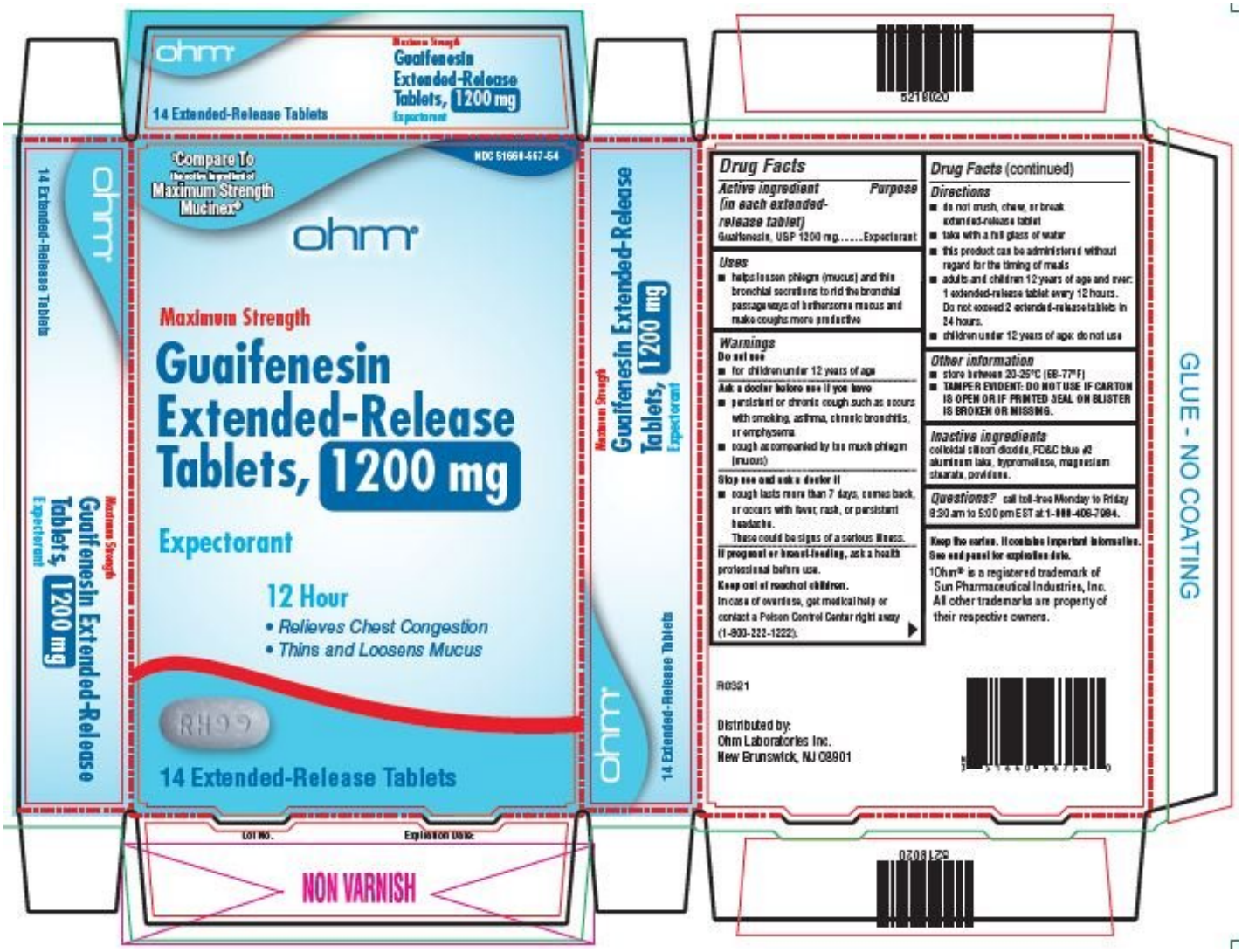
Package/Label Principal Display Panel



Package/Label Principal Display Panel



Principal Display Panel



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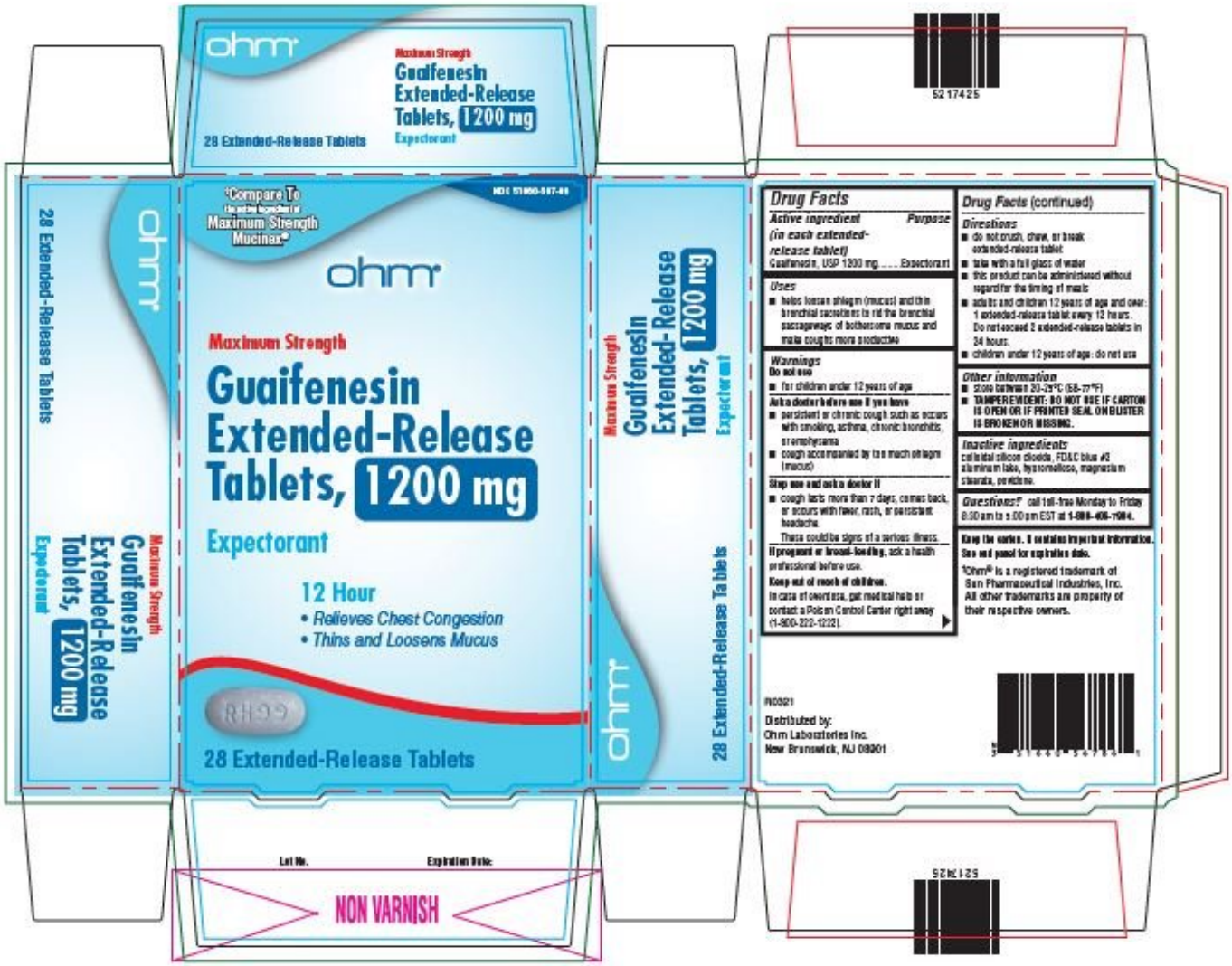
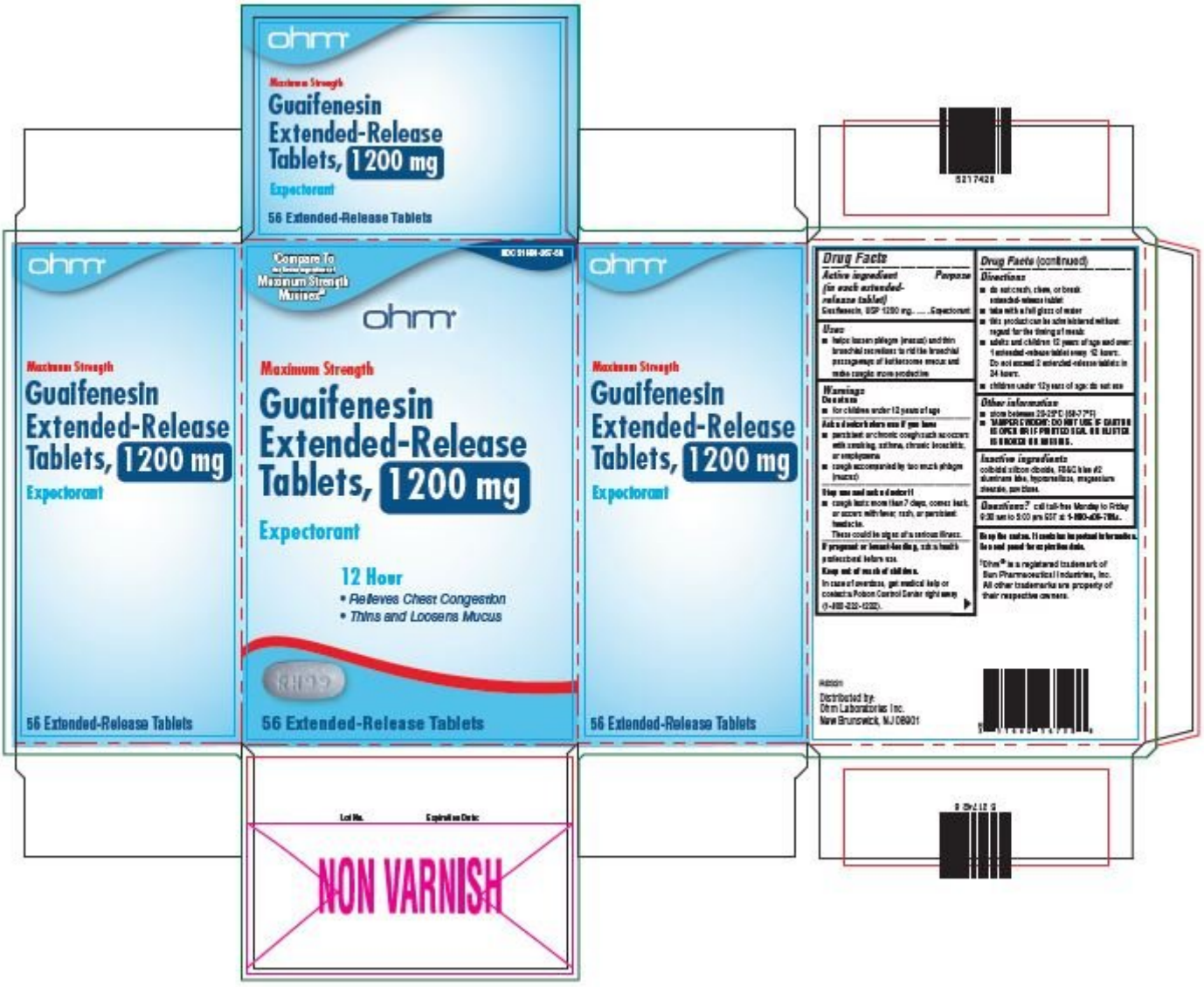


Principal Display Panel



GUAIFENESIN

guaifenesin tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51660-566
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

Product Characteristics

Color	WHITE (blue/white mottled)	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	RH;98
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51660-566-41	40 in 1 CARTON; Type 0: Not a Combination Product	04/01/2022	
2	NDC:51660-566-21	20 in 1 CARTON; Type 0: Not a Combination Product	04/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209254	04/01/2022	

GUAIFENESIN

guaifenesin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51660-567
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

Product Characteristics			
Color	WHITE (blue/white mottled)	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	RH;99
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51660-567-54	14 in 1 CARTON; Type 0: Not a Combination Product	04/01/2022	
2	NDC:51660-567-86	28 in 1 CARTON; Type 0: Not a Combination Product	04/01/2022	
3	NDC:51660-567-58	56 in 1 CARTON; Type 0: Not a Combination Product	04/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209254	04/01/2022	

Labeler - Ohm Laboratories, Inc. (184769029)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories, Inc.		184769029	MANUFACTURE(51660-566, 51660-567) , ANALYSIS(51660-566, 51660-567) , PACK(51660-566, 51660-567)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650456002	MANUFACTURE(51660-566, 51660-567)

Revised: 12/2022 Ohm Laboratories, Inc.