

**GUAIFENESIN AND PSEUDOEPHEDRINE HCL- guaifenesin and pseudoephedrine hcl tablet, extended release**

**Dr. Reddys Laboratories Limited**

-----

**Drug Facts**

**Active ingredient(s)**

Guaifenesin USP, 600 mg.....Expectorant  
Pseudoephedrine HCl USP, 60 mg.....Nasal Decongestant  
Guaifenesin USP, 1200 mg.....Expectorant  
Pseudoephedrine HCl USP, 120 mg.....Nasal Decongestant

**Purpose**

Expectorant and Nasal Decongestant

**Use(s)**

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of both some mucus and make coughs more productive
- temporarily relieves nasal congestion due to:
  - common cold
  - hay fever
  - upper respiratory allergies
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- temporarily relieves sinus congestion and pressure\_

**Warnings**

**Do not use**

if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson’s disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

- cough accompanied by too much phlegm (mucus)

### **When using this product**

- do not use more than directed

### **Stop use and ask doctor if**

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days, come back or occur with a fever, rash, or persistent headache. These could be signs of a serious illness.

### **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 (1-800-222-1222).

### **Directions**

- do not crush, chew, or break tablet
- take with a full glass of water
- this product can be administered without regard for timing of meals
- children under 12 years of age: do not use

### **For 600 mg/60 mg**

- adults and children 12 years and older: 2 tablets every 12 hours; not more than 4 tablets in 24 hours

### **For 1200 mg/120 mg**

- adults and children 12 years and older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours

### **Other information**

- tamper evident: do not use if carton is open or if printed seal on blister is broken or missing.

### **Storage**

- store between 20°-25°C (68°-77°F)

### **Inactive ingredients**

FD & C yellow #6, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, silicon dioxide.

### **Questions**

call 1-888-375-3784

You may also report side effect to this phone number.

**Keep the carton.**

**It contains important information.**

See end panel for expiration date.

Manufactured by:

**Dr. Reddy's Laboratories Limited**

Srikakulam – 532 409 INDIA

**Principal Display Panel**

Guaifenesin and Pseudoephedrine HCl ER Tablets 600 mg/60 mg:

**Drug Facts (continued)**

**Other Information**

- Keep out of reach of children. Do not use if carton is open or if printed seal on blister is broken or missing.
- Keep this and all other medicines out of the reach of children. This product contains acetaminophen. Do not use if you are taking other medicines that contain acetaminophen. Do not use if you are taking other medicines that contain pseudoephedrine.
- Keep this and all other medicines out of the reach of children. This product contains acetaminophen. Do not use if you are taking other medicines that contain acetaminophen. Do not use if you are taking other medicines that contain pseudoephedrine.

**Drug Facts (continued)**

**Warnings**

- Do not use if you are taking other medicines that contain acetaminophen. Do not use if you are taking other medicines that contain pseudoephedrine.
- Do not use if you are taking other medicines that contain acetaminophen. Do not use if you are taking other medicines that contain pseudoephedrine.

**Directions**

Adults and children 12 years and older: 2 tablets every 12 hours. Not more than 4 tablets in 24 hours.

Children under 12 years of age: Do not use.

**Other Information**

Keep out of reach of children. Do not use if carton is open or if printed seal on blister is broken or missing.

**Drug Facts (continued)**

**Warnings**

- Do not use if you are taking other medicines that contain acetaminophen. Do not use if you are taking other medicines that contain pseudoephedrine.
- Do not use if you are taking other medicines that contain acetaminophen. Do not use if you are taking other medicines that contain pseudoephedrine.

**Directions**

Adults and children 12 years and older: 2 tablets every 12 hours. Not more than 4 tablets in 24 hours.

Children under 12 years of age: Do not use.

**Other Information**

Keep out of reach of children. Do not use if carton is open or if printed seal on blister is broken or missing.

Do not use if carton is open or if printed seal on blister is broken or missing


**Guaifenesin 600 mg and Pseudoephedrine HCl 60 mg**  
**Extended-Release Tablets**  
**Expectorant & Nasal Decongestant**

NDC 55111-798-09

**9 Extended-Release Tablets**

**Guaifenesin 600 mg and Pseudoephedrine HCl 60 mg**  
**Extended-Release Tablets**  
**Expectorant & Nasal Decongestant**

**Clears Nasal/Sinus Congestion**  
**Thins and Loosens Mucus**



12 HOUR

Not actual size

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

Manufactured by:  
**Dr. Reddy's Laboratories Limited**  
 Srikakulam – 532 409 INDIA

Lot  
 Exp

Guaifenesin and Pseudoephedrine HCl ER Tablets 600 mg/60 mg: 18s (1x18s)

**Drug Facts (continued)**

**Other Information**

- Keep this and all other medicines out of the reach of children.
- Do not use if you are now taking a prescription drug that contains an MAOI, ask a doctor or pharmacist before taking this product.

**Drug Facts (continued)**

**Warnings**

- Do not use if you are now taking a prescription drug that contains an MAOI, ask a doctor or pharmacist before taking this product.
- Do not use if you are now taking a prescription drug that contains an MAOI, ask a doctor or pharmacist before taking this product.

**Directions**

12 hours; not more than 4 tablets in 24 hours adults and children 12 years and older: 2 tablets every 12 hours; not more than 4 tablets in 24 hours

**Drug Facts (continued)**

**Active Ingredients**

Guaifenesin USP, 600 mg  
Pseudoephedrine HCl USP, 60 mg (in each extended-release tablet)

**Purpose**

Expectorant

**Drug Facts (continued)**

**When using this product**

- do not use more than directed
- do not use more than directed

**Stop use and ask a doctor if**

- symptoms do not get better within 7 days, come back or occur with a fever, rash, or persistent headache.
- these could be signs of a serious illness.

**If pregnant or 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 (1-800-222-1222).

**Other Information**

FD & C yellow #6, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, silicon dioxide

**Questions?** call 1-888-375-3784

You may also report side effects to this phone number.

**Drug Facts (continued)**

**Other Information**

- Keep this and all other medicines out of the reach of children.
- Do not use if you are now taking a prescription drug that contains an MAOI, ask a doctor or pharmacist before taking this product.

**Drug Facts (continued)**

**Warnings**

- Do not use if you are now taking a prescription drug that contains an MAOI, ask a doctor or pharmacist before taking this product.
- Do not use if you are now taking a prescription drug that contains an MAOI, ask a doctor or pharmacist before taking this product.

**Directions**

12 hours; not more than 4 tablets in 24 hours adults and children 12 years and older: 2 tablets every 12 hours; not more than 4 tablets in 24 hours

**Drug Facts (continued)**

**Active Ingredients**

Guaifenesin USP, 600 mg  
Pseudoephedrine HCl USP, 60 mg (in each extended-release tablet)

**Purpose**

Expectorant

**Drug Facts (continued)**

**When using this product**

- do not use more than directed
- do not use more than directed

**Stop use and ask a doctor if**

- symptoms do not get better within 7 days, come back or occur with a fever, rash, or persistent headache.
- these could be signs of a serious illness.

**If pregnant or 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 (1-800-222-1222).

**Other Information**

FD & C yellow #6, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, silicon dioxide

**Questions?** call 1-888-375-3784


You may also report side effects to this phone number.

Do not use if carton is open or if printed seal on blister is broken or missing

**Guaifenesin 600 mg and Pseudoephedrine HCl 60 mg**  
**Extended-Release Tablets**  
**Expectorant & Nasal Decongestant**

Manufactured by:  
**Dr. Reddy's Laboratories Limited**  
Srikakulam - 532 409 INDIA

Lot  
Exp




NDC 55111-798-35

**18 Extended-Release Tablets**


**Guaifenesin 600 mg and Pseudoephedrine HCl 60 mg**  
**Extended-Release Tablets**

**Expectorant & Nasal Decongestant**

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



**DR. REDDY'S**



**12 HOUR**

Not actual size


- Clears Nasal/Sinus Congestion
- Thins and Loosens Mucus
- Immediate and Extended Release

Do not use if carton is open or if printed seal on blister is broken or missing

**Guaifenesin 600 mg and Pseudoephedrine HCl 60 mg**  
**Extended-Release Tablets**  
**Expectorant & Nasal Decongestant**

Manufactured by:  
**Dr. Reddy's Laboratories Limited**  
Srikakulam - 532 409 INDIA

Lot  
Exp



Guaifenesin and Pseudoephedrine HCl ER Tablets 600 mg/60 mg: 36s (2x18s)

<p><b>Drug Facts (continued)</b></p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>Keep out of reach of children.</li> <li>Keep out of reach of children.</li> <li>Keep out of reach of children.</li> <li>Keep out of reach of children.</li> <li>Keep out of reach of children.</li> </ul> <p><b>Questions?</b> call 1-888-375-3784</p> <p>You may also report side effects to this phone number.</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>Keep out of reach of children.</li> <li>Keep out of reach of children.</li> <li>Keep out of reach of children.</li> <li>Keep out of reach of children.</li> <li>Keep out of reach of children.</li> </ul> <p><b>Questions?</b> call 1-888-375-3784</p> <p>You may also report side effects to this phone number.</p>
<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>12 hours; not more than 4 tablets in 24 hours.</li> <li>adults and children 12 years and older: 2 tablets every 12 hours; not more than 4 tablets in 24 hours.</li> <li>adults and children 12 years and older: 2 tablets every 12 hours; not more than 4 tablets in 24 hours.</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>12 hours; not more than 4 tablets in 24 hours.</li> <li>adults and children 12 years and older: 2 tablets every 12 hours; not more than 4 tablets in 24 hours.</li> <li>adults and children 12 years and older: 2 tablets every 12 hours; not more than 4 tablets in 24 hours.</li> </ul>
<p><b>Drug Facts (continued)</b></p> <p><b>Warnings</b></p> <ul style="list-style-type: none"> <li>Do not use if you are no taking a prescription drug.</li> <li>Do not use if you are no taking a prescription drug.</li> <li>Do not use if you are no taking a prescription drug.</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Warnings</b></p> <ul style="list-style-type: none"> <li>Do not use if you are no taking a prescription drug.</li> <li>Do not use if you are no taking a prescription drug.</li> <li>Do not use if you are no taking a prescription drug.</li> </ul>
<p><b>Drug Facts (continued)</b></p> <p><b>Active ingredients</b></p> <p>Guaifenesin USP, 600 mg</p> <p>Pseudoephedrine HCl USP, 60 mg</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Active ingredients</b></p> <p>Guaifenesin USP, 600 mg</p> <p>Pseudoephedrine HCl USP, 60 mg</p>

Manufactured by:  
**Dr. Reddy's Laboratories Limited**  
 Srikakulam - 532 409 INDIA

Lot  
 Exp

Do not use if carton is open or if printed seal on blister is broken or missing

**Guaifenesin 600 mg and Pseudoephedrine HCl 60 mg**  
**Extended-Release Tablets**  
**Expectorant & Nasal Decongestant**

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

**DR. REDDY'S**

NDC 55111-798-41

**36 Extended-Release Tablets**

**Guaifenesin 600 mg and Pseudoephedrine HCl 60 mg**  
**Extended-Release Tablets**

**Expectorant & Nasal Decongestant**

- Clears Nasal/Sinus Congestion
- Thins and Loosens Mucus
- Immediate and Extended Release

Pantone 355 C

Pantone 50% 355 C

Guaifenesin and Pseudoephedrine HCl ER Tablets 1200 mg/120 mg:

Dr. Reddy's Laboratories Limited  
Srikakulam - 532409 INDIA  
Manufactured by:

**Drug Facts**  
(In each extended-release tablet)  
Guafenesin HCl 1200 mg  
Pseudoephedrine HCl 120 mg  
Nasal Decongestant

**Active Ingredients**

**Uses**  
Temporary relief of the signs and symptoms of nasal congestion due to rhinitis (runny nose), sinusitis (inflammation of the sinus cavities), and the common cold.  
Use this medicine for as long as needed to relieve your symptoms.  
Use this medicine as directed on the label.  
Use this medicine for as long as needed to relieve your symptoms.

**Warnings**  
Do not use if you have taken any MAO inhibitor (MAOI) (or other drugs for depression, Parkinson's disease, or other conditions) or alcohol during the last 14 days before starting this medicine.  
Do not use if you have a known hypersensitivity to any of the ingredients in this medicine.  
Do not use if you are pregnant or breastfeeding.  
Do not use if you are taking any other medicines for nasal congestion.

**Directions**  
Swallow 1 or 2 tablets 2 or 3 times a day with or without food. Do not crush or chew the tablets.  
Do not use for more than 7 days. If symptoms do not improve, ask your doctor.  
Do not use for more than 10 days. If symptoms do not improve, ask your doctor.


**Other Information**  
Contains 12 extended-release tablets.  
Keep out of reach of children.

**Contains 12 extended-release tablets.**  
Keep out of reach of children.

**Other Information**  
Contains 12 extended-release tablets.  
Keep out of reach of children.

Lot

Exp



**Drug Facts (continued)**  
When using this product, do not use other nasal decongestant sprays. Stop use as directed or if symptoms do not improve within 7 days, come back or call with the number on the label. If symptoms do not improve within 7 days, come back or call with the number on the label.

Do not use if carton is open or if printed seal on blister is broken or missing

**Guafenesin 1200 mg and Pseudoephedrine HCl 120 mg**  
**Extended-Release Tablets**  
**Expectorant & Nasal Decongestant**

DR. REDDY'S

NDC 55111-799-12

**12 Extended-Release Tablets**

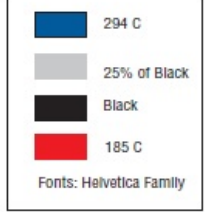
**MAXIMUM STRENGTH**  
**Guafenesin 1200 mg and Pseudoephedrine HCl 120 mg**  
**Extended-Release Tablets**

**Expectorant & Nasal Decongestant**

 **12 HOUR**

- Clears Nasal/Sinus Congestion
- Thins and Loosens Mucus

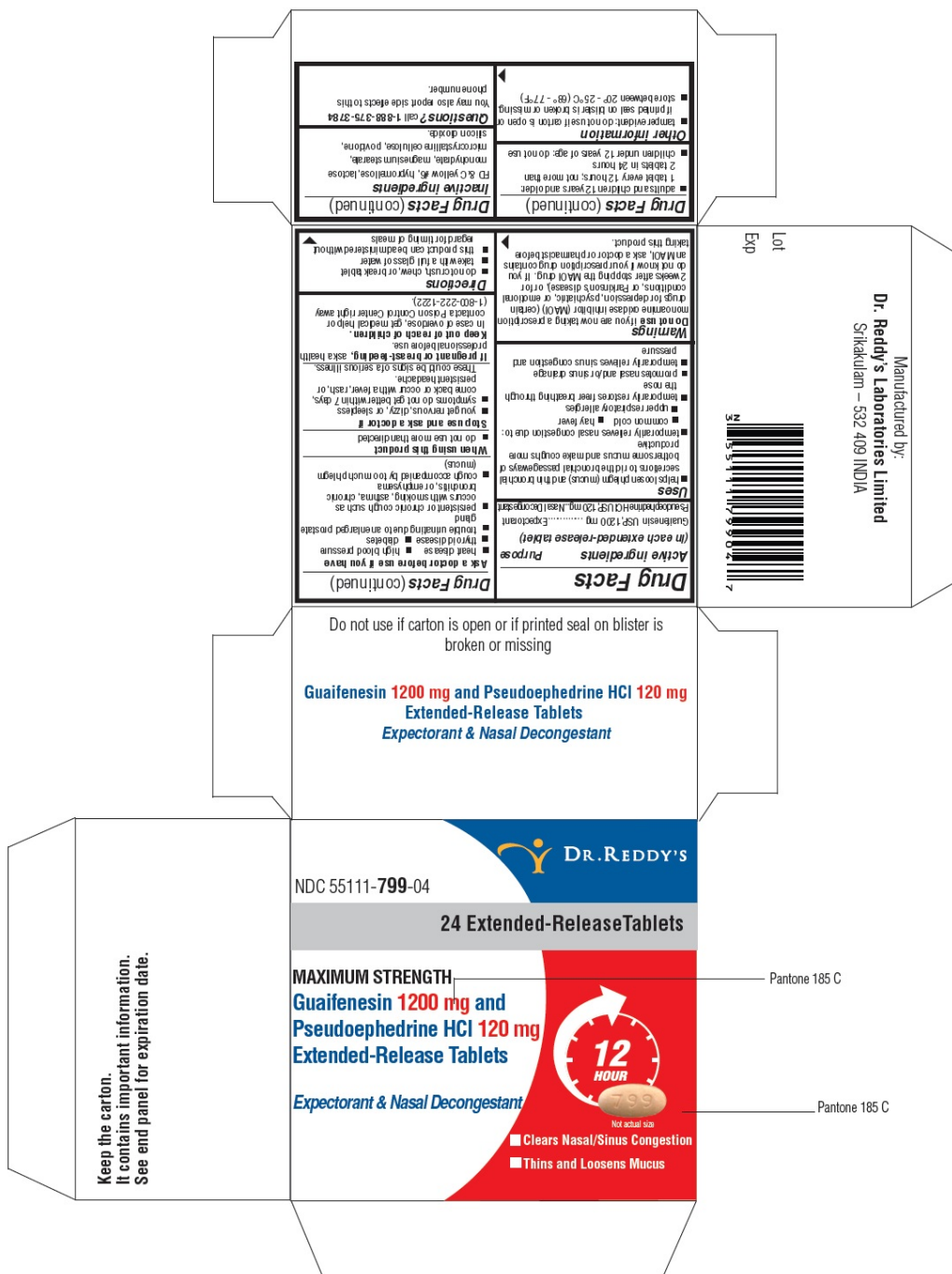
Keep the carton. It contains important information. See end panel for expiration date.



**Labeling Format Information:**  
Fonts: Helvetica cond. medium, bold, bold oblique  
Drug Facts: 14 pt  
Header: 8 pt  
Subheader: 6 pt  
Body Text: 6 pt  
Drugs Facts (continued): NA  
Leading: 7 pt  
Bullets: 5 pt  
Barlines: 2.5 pt  
Hairlines: 0.5 pt

**NOTE: This Blister Carton is fit to paper print**

Guafenesin and Pseudoephedrine HCl ER Tablets 1200 mg/120 mg: 24s (4x6s)



## GUAIFENESIN AND PSEUDOEPHEDRINE HCL

guaifenesin and pseudoephedrine hcl tablet, extended release

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55111-798
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	600 mg
Pseudoephedrine Hydrochloride (UNII: 6 V9 V2RYJ8N) (Pseudoephedrine -	Pseudoephedrine	60 mg

UNII:7CUC9DDI9F)

Hydrochloride

00 mg

**Inactive Ingredients**

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

**Product Characteristics**

Color	ORANGE	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	RDY;798
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55111-798-09	1 in 1 CARTON	12/29/2017	
1		9 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:55111-798-18	2 in 1 CARTON	12/29/2017	
2		9 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:55111-798-36	4 in 1 CARTON	12/29/2017	
3		9 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:55111-798-35	1 in 1 CARTON	01/23/2020	
4		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:55111-798-41	2 in 1 CARTON	03/11/2020	
5		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208369	12/29/2017	

**GUAIFENESIN AND PSEUDOEPHEDRINE HCL**

guaifenesin and pseudoephedrine hcl tablet, extended release

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55111-799
Route of Administration	ORAL		



**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Guaifenesin</b> (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	1200 mg
<b>Pseudoephedrine Hydrochloride</b> (UNII: 6 V9 V2RYJ8 N) (Pseudoephedrine - UNII:7CUC9DDI9F)	Pseudoephedrine Hydrochloride	120 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D6IU)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

**Product Characteristics**

<b>Color</b>	ORANGE	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	22mm
<b>Flavor</b>		<b>Imprint Code</b>	RDY;799
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55111-799-12	1 in 1 CARTON	12/29/2017	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:55111-799-24	2 in 1 CARTON	12/29/2017	
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:55111-799-36	3 in 1 CARTON	12/29/2017	
3		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:55111-799-04	4 in 1 CARTON	12/29/2017	
4	NDC:55111-799-06	6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208369	12/29/2017	

**Labeler** - Dr. Reddys Laboratories Limited (650562841)**Establishment**

Name	Address	ID/FEI	Business Operations
Dr. Reddys Laboratories Limited (SEZ		060027244	manufacture(55111-798, 55111-799) , analysis(55111-798, 55111-

