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 bother 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 extended-release 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 extended-release tablets every 12 hours; not more than 4 extended-release tablets in 24 hours

For 1200 mg/120 mg

■ adults and children 12 years and older: 1 extended-release tablet every 12 hours; not more than 2 extended-release 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.

DISTRIBUTED BY:

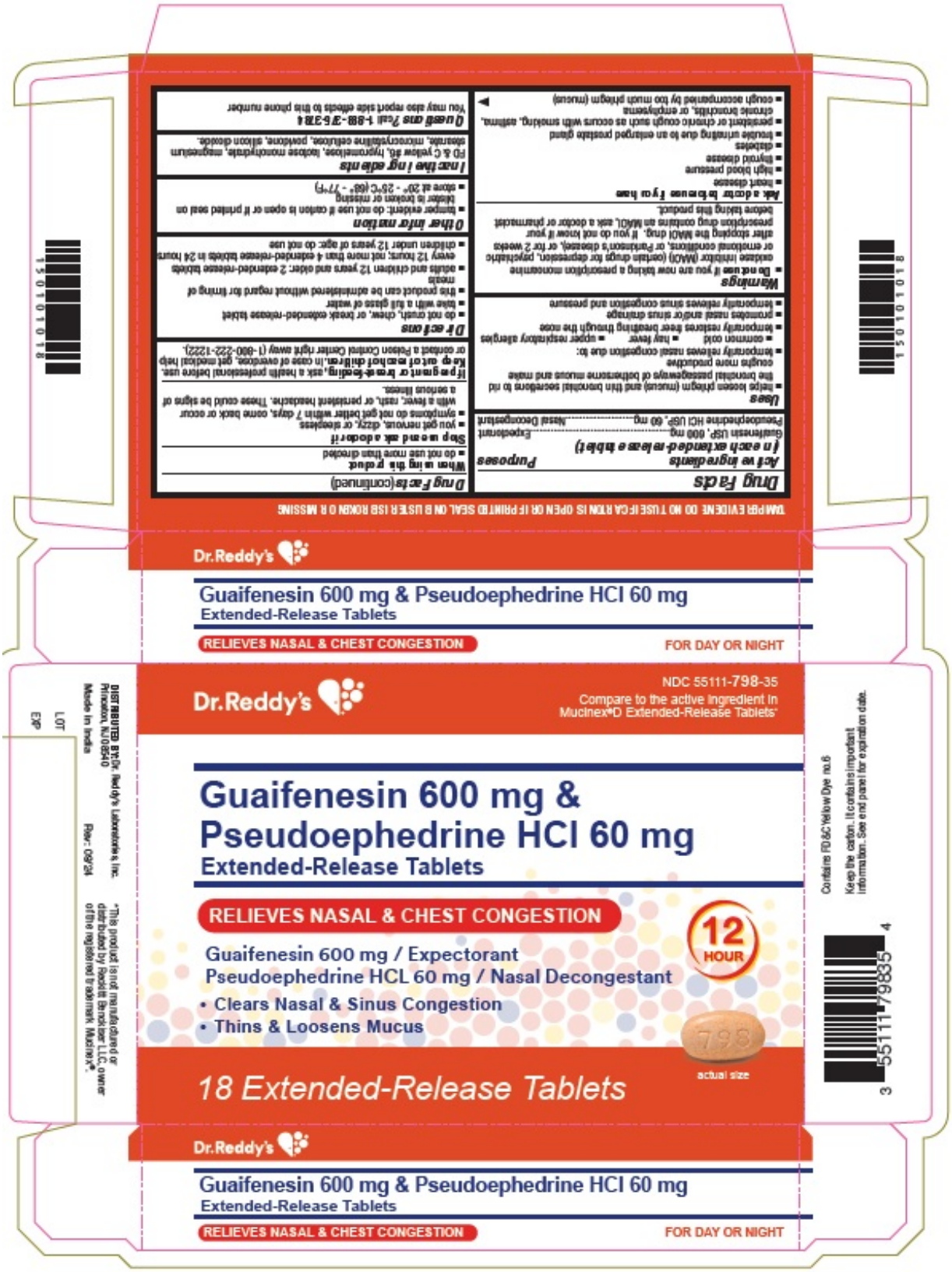
Dr. Reddy’s Laboratories Inc.,

Princeton, NJ – 08540

Made in India

Principal Display Panel

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



Guaifenesin and Pseudoephedrine HCl ER Tablets 1200 mg/120 mg: 24s (2x12s)


Drug Facts
Active ingredients (in each extended-release tablet)
Purposes
Guaifenesin USP, 1200 mg ..... Expectorant
Pseudoephedrine HCl USP, 120 mg ..... Nasal Decongestant
Uses
■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome 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 you have
■ 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)
Drug Facts (continued)
When using this product
■ do not use more than directed
Stop use and ask a 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.
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
■ do not crush, chew, or break extended-release tablet
■ take with a full glass of water
■ this product can be administered without regard for timing of meals
■ adults and children 12 years and older: 1 extended-release tablet every 12 hours; not more than 2 extended-release tablets in 24 hours
■ children under 12 years of age: do not use
Other information
■ tamper evident: do not use if carton is open or if printed seal on blister is broken or missing
■ store at 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 effects to this phone number.
TAMPER EVIDENT: DO NOT USE IF CARTON IS OPEN OR IF PRINTED SEAL ON BLISTER IS BROKEN OR MISSING
Dr.Reddy's
Maximum Strength
Guaifenesin 1200 mg & Pseudoephedrine HCl 120 mg
Extended-Release Tablets
RELIEVES NASAL & CHEST CONGESTION
FOR DAY OR NIGHT
Dr.Reddy's
NDC 55111-799-24
Compare to the active ingredient in Maximum Strength Mucinex®D Tablets*
Maximum Strength
Guaifenesin 1200 mg & Pseudoephedrine HCl 120 mg
Extended-Release Tablets
RELIEVES NASAL & CHEST CONGESTION
12 HOUR
Guaifenesin 1200 mg / Expectorant
Pseudoephedrine HCL 120 mg / Nasal Decongestant
• Clears Nasal & Sinus Congestion
• Thins & Loosens Mucus
799
actual size
24 Extended-Release Tablets
Dr.Reddy's
Maximum Strength
Guaifenesin 1200 mg & Pseudoephedrine HCl 120 mg
Extended-Release Tablets
RELIEVES NASAL & CHEST CONGESTION
FOR DAY OR NIGHT
DISTRIBUTED BY: Dr. Reddy's Laboratories, Inc.
Princeton, NJ 08540
Made in India
Rev: 09/24
*This product is not manufactured or distributed by Reckitt Benckiser LLC, owner of the registered trademark Mucinex®.
LOT
EXP
Contains FD&C Yellow Dye no.6
Keep the carton. It contains important information. See end panel for expiration date.
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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: 6V9V2RYJ8N) (Pseudoephedrine - UNII:7CUC9DDI9F)	Pseudoephedrine Hydrochloride	60 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
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	1200 mg
Pseudoephedrine Hydrochloride (UNII: 6V9V2RYJ8N) (Pseudoephedrine - UNII:7CUC9DDI9F)	Pseudoephedrine Hydrochloride	120 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**	22mm
Flavor		**Imprint Code**	RDY;799
Contains			

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 UNIT)		860037244	manufacture(55111-798, 55111-799) , analysis(55111-798, 55111-799)

Revised: 10/2025 Dr. Reddys Laboratories Limited