

GUAIFENESIN - guaifenesin tablet, extended release
RITE AID CORPORATION

Drug Facts

Active ingredient

(in each extended-release tablet)

Guaifenesin USP 1200 mg

Purpose

Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome 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 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 tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: 1 tablet every 12 hours. Do not exceed 2 tablets in 24 hours.
- children under 12 years of age: do not use

Other information

- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, and pregelatinised starch (maize)

Questions?

1-855-274-4122 (Monday – Friday 8:30 AM to 5:00 PM EST) You may also report side effects to this phone number.

DISTRIBUTED BY:RITE AID,
30 HUNTER LANE, CAMP HILL,
PA 17011 **www.riteaid.com**

MADE IN INDIA

Code: AP/DRUGS/04/2016

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1200 mg Blister Carton (14 (1 x 14) Tablets)

Compare to the active Ingredient in Maximum Strength Mucinex[®]*

NDC 11822-4260-1

**MAXIMUM STRENGTH
MUCUS
RELIEF
GUAIFENESIN EXTENDED-RELEASE
TABLETS 1200 mg**

EXPECTORANT

Relieves chest congestion
Thins & loosens mucus

**12
HOUR**

ACTUAL SIZE

**14
EXTENDED-RELEASE
TABLETS**



GUAIFENESIN

guaifenesin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-4260
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)	
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)	
HYPROMELLOSE 2910 (10000 MPA.S) (UNII: 0HO1H52958)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
POVIDONE K25 (UNII: K0KQV10C35)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (white to off-white)	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	L;69
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-4260-1	1 in 1 CARTON	06/29/2022	
1		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11822-4260-2	2 in 1 CARTON	06/29/2022	
2		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:11822-4260-3	3 in 1 CARTON	06/29/2022	
3		14 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	ANDA210453	06/29/2022	

Labeler - RITE AID CORPORATION (014578892)

Registrant - Aurohealth LLC (078728447)**Establishment**

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(11822-4260) , MANUFACTURE(11822-4260)

Revised: 12/2023

RITE AID CORPORATION