GUAIFENESIN - guaifenesin tablet, extended release VESPYR BRANDS, INC.

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 or comments?

call toll-free **1-855-874-0970** (English/Spanish) weekdays. You may also report side effects to this phone number.

DISTRIBUTED BY:

Vespyr Brands[®], Inc. East Windsor, NJ 08520

Made in India

Code: AP/DRUGS/04/2016

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1200 mg Blister Carton (21 Tablets)

12 NDC 71179-002-21

HR

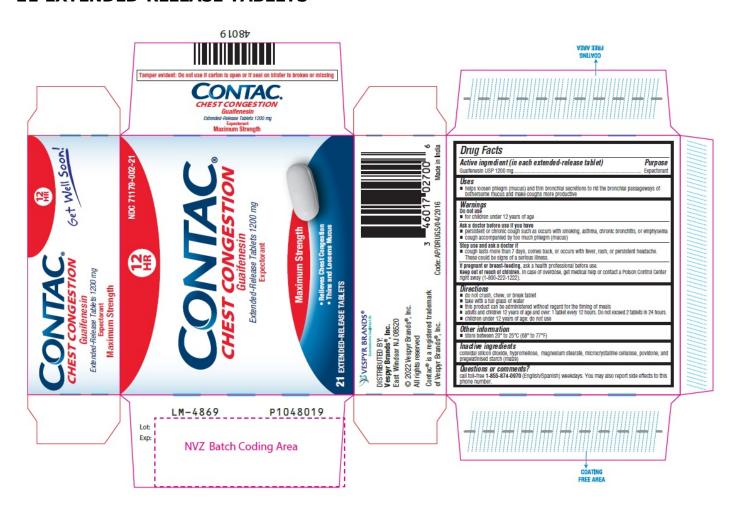
CONTAC® CHEST CONGESTION

Guaifenesin Extended-Release Tablets 1200 mg Expectorant

Maximum Strength

- Relieves Chest Congestion
- Thins And Loosens Mucus

21 EXTENDED-RELEASE TABLETS



GUAIFENESIN

guaifenesin tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71179-002
Route of Administration	ORAL		
Active Ingredient/Active Mojety			

Active ingredient/Active Molety			
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			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71179-002- 21	3 in 1 CARTON	06/27/2022	
1		7 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	06/27/2022	

Labeler - VESPYR BRANDS, INC. (118094893)

Registrant - Aurohealth LLC (078728447)

Establishment				
Name	Address	ID/FEI	Business Operations	
APL HEALTHCARE LIMITED		650918514	ANALYSIS(71179-002), MANUFACTURE(71179-002)	

Revised: 12/2023 VESPYR BRANDS, INC.