

EXCAUGH- guaifenesin tablet
FORTUNE PHARMACAL COMPANY, LIMITED

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredients (in each tablet)

Guaifenesin 100 mg

Purpose

Expectorant

Uses

helps loosen phlegm (mucus) and thin bronchial secretions to:
 rid the bronchial passageways of bothersome mucus
 make coughs more productive

Warnings

Ask a doctor before use if the user has

a persistent or chronic cough such as occurs with:

- smoking
- asthma
- chronic bronchitis
- emphysema

a cough that is accompanied by excessive phlegm (mucus)
a high fever

Stop use and ask a doctor if

any of the following occurs (these could be signs of a serious condition):

- cough persists for more than 1 week
- cough tends to recur
- cough is accompanied by a fever, rash, or persistent headache

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.

Directions

adults and children 12 years of age and over: take 2 to 4 tablets every 4 hours, not to exceed 24 tablets (2,400 mg) in 24 hours

children 6 to under 12 years of age: take 1 to 2 tablets every 4 hours, not to exceed 12 tablets (1,200 mg) in 24 hours

children under 6 years of age: consult a doctor

Other information

- Phenylketonurics: Contains Phenylalanine 3.929 mg Per Tablet
- keep tightly sealed
- store between 20 to 25° C (68 to 77° F)

Inactive ingredients aspartame, colloidal silicon dioxide, corn starch, D&C yellow no.10 aluminum lake, lactose monohydrate, magnesium stearate, povidone K30, sodium starch glycolate.

Questions or comments?(888) 221-3496 M-F 9 am to 5 pm
 you may also report serious side effects to this phone number

EXCAUGH
 Guaifenesin - Expectorant
 NDC 51467-009-02
 36 Tablets



EXCAUGH
 guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51467-009
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	FORTUNE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51467-009-01	2 in 1 BOX	04/26/2016	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51467-009-02	3 in 1 BOX	03/21/2018	
2		12 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
OTC monograph final	part341	04/26/2016	

Labeler - FORTUNE PHARMACAL COMPANY, LIMITED (686280561)**Establishment**

Name	Address	ID/FEI	Business Operations
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Revised: 10/2018

FORTUNE PHARMACAL COMPANY, LIMITED