SELECT BRAND MUCUS RELIEF - guaifenesin tablet
Select Brand Distributors

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 ingredient (per tablet)

Guaifenesin 200mg

Purpose

Expectorant

Uses

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

Warnings

Ask doctor before use if you have

- persistent or chronic cough, such as occurs with smoking, asthma, bronchitis or emphysema
- cough is accompanied by excessive phlegm (mucus)

Stop use and ask doctor if

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

A persistent cough may be a sign of a serious condition.

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 immediately.

Directions

- **Adults and children 12 years of age and over:** take 1 to 2 tablets every 4 hours as needed
- **Children 6 to 10 under 12 years of age:** take 1/2 to 1 tablet every 4 hours as needed
- **Children under 6 years of age:** consult a doctor

Do not exceed 6 doses in a 24 hour period or as directed by a doctor

Other Information

store at 15°-30°C (59°-86°F)

Inactive ingredients

FD C red No. 40 (Al-lake), magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, silicon dioxide, sodium starch glycolate, stearic acid.

SELECT BRAND MUCUS RELIEF

guaifenesin tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:15127-129
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POVIDONE (UNII: FZ989GH94E)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics			
Color	red (rose)	**Score**	2 pieces
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	151
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15127-129-60	1 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/26/2014	

Labeler - Select Brand Distributors (043562370)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment

Name	Address	ID/FEI	Business Operations
Reese Pharmaceutical Co		004172052	relabel(15127-129) , repack(15127-129)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc		078301063	manufacture(15127-129)

Revised: 9/2014 Select Brand Distributors