ORGAN-I NR- guaifenes in tablet Rebel Distributors Corp

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.

ORGAN-INR

Active ingredient

Guaifenesin, USP 200 mg

Purpose

Expectorant

Use

helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

Warnings

Ask a doctor before use if you have

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Stop use and ask a doctor if cough lasts more than 7 days, comes back or is accompanied by fever, rash, or persistent headache. These could be signs 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 right away.

Directions

- do not take more than 6 doses in any 24-hour period ...
- this adult product is not intended for use in children under 12 years of age

adults and children 1 - 2 tablets
12 years and over every 4 hours
children under do not use
12 years

Other information

• store at 15° to 30°C (59° to 86°F)

You may report serious side effects to: 130 Vintage Drive, Huntsville, AL 35811.

Inactive ingredients

D&C red #30 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyvinylpyrrolidine, pregelatinized starch, silicon dioxide, stearic acid

Made in the **USA** for Qualitest Pharmaceuticals Huntsville, AL 35811

Rev. 3/11 R5 8080143 4740

Repackaged by:

Rebel Distributors Corp

Thousand Oaks, CA 91320

PRINCIPAL DISPLAY PANEL



ORGAN-I NR guaifenesin tablet Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:21695-048(NDC:0603-4886)

Route of Administration

ORAL

Active Ingredient/Active Moiety

retive ingredient violety			
	Ingredient Name	Basis of Strength	Strength
	GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients		
Ingredient Name	Strength	
D&C RED NO. 30 (UNII: 2S42T2808B)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MALTO DEXTRIN (UNII: 7CVR7L4A2D)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
STEARIC ACID (UNII: 4ELV7Z65AP)		

Product Characteristics			
Color	RED (rose colored)	Score	2 pieces
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	4740;V
Contains			

I	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-048-30	30 in 1 BOTTLE, PLASTIC		
2	NDC:21695-048-40	40 in 1 BOTTLE, PLASTIC		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	07/01/2002		

Labeler - Rebel Distributors Corp (118802834)

Establishment			
Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 7/2011 Rebel Distributors Corp