GUAIFENESIN EXTENDED-RELEASE TABLETS, 600MG- guaifenesin extended-release tablet
GUAIFENSIN EXTENDED-RELEASE TABLETS, 1200 MG- guaifensin extended-release tablet
Granules India Ltd

Guaifenesin Extended-Release Tablets 600mg and 1200mg

ACTIVE INGREDIENT(S)

Guaifenesin 600 mg (for 600mg)

Guaifenesin 1200 mg (for 1200 mg)

PURPOSE

Expectorant

USE(S)

- 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 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.

PREGNANCY/BREASTFEEDING

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 timing of meals
- adults and children 12 years of age and over: 1 or 2 tablets every 12 hours. Do not exceed 4 tablets in 24 hours(For 600mg)
- adults and children 12 years of age and over: 1 tablet every 12 hours. Do not exceed 2 tablets in 24 hours.(For 1200mg)
- children under 12 years of age: do not use

OTHER INFORMATION

Tamper evident: Do not use if carton is open or if printed seal on blister is broken or missing.

INACTIVE INGREDIENTS

carbomer homopolymer type B; hypromellose, Lake of FD&C Blue 1, magnesium stearate, microcrystalline cellulose; sodium starch glycolate

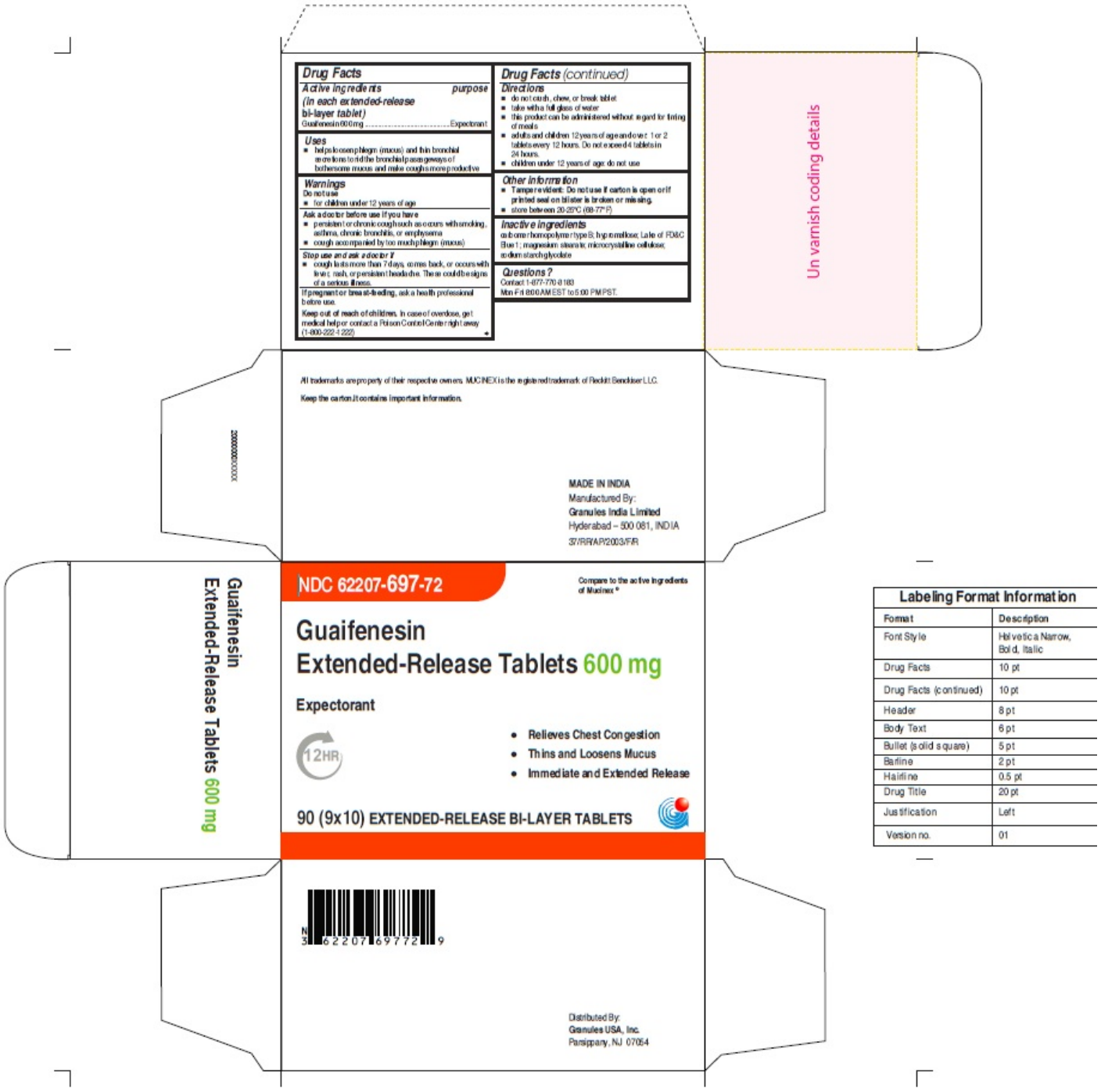
QUESTIONS OR COMMENTS

Contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST.

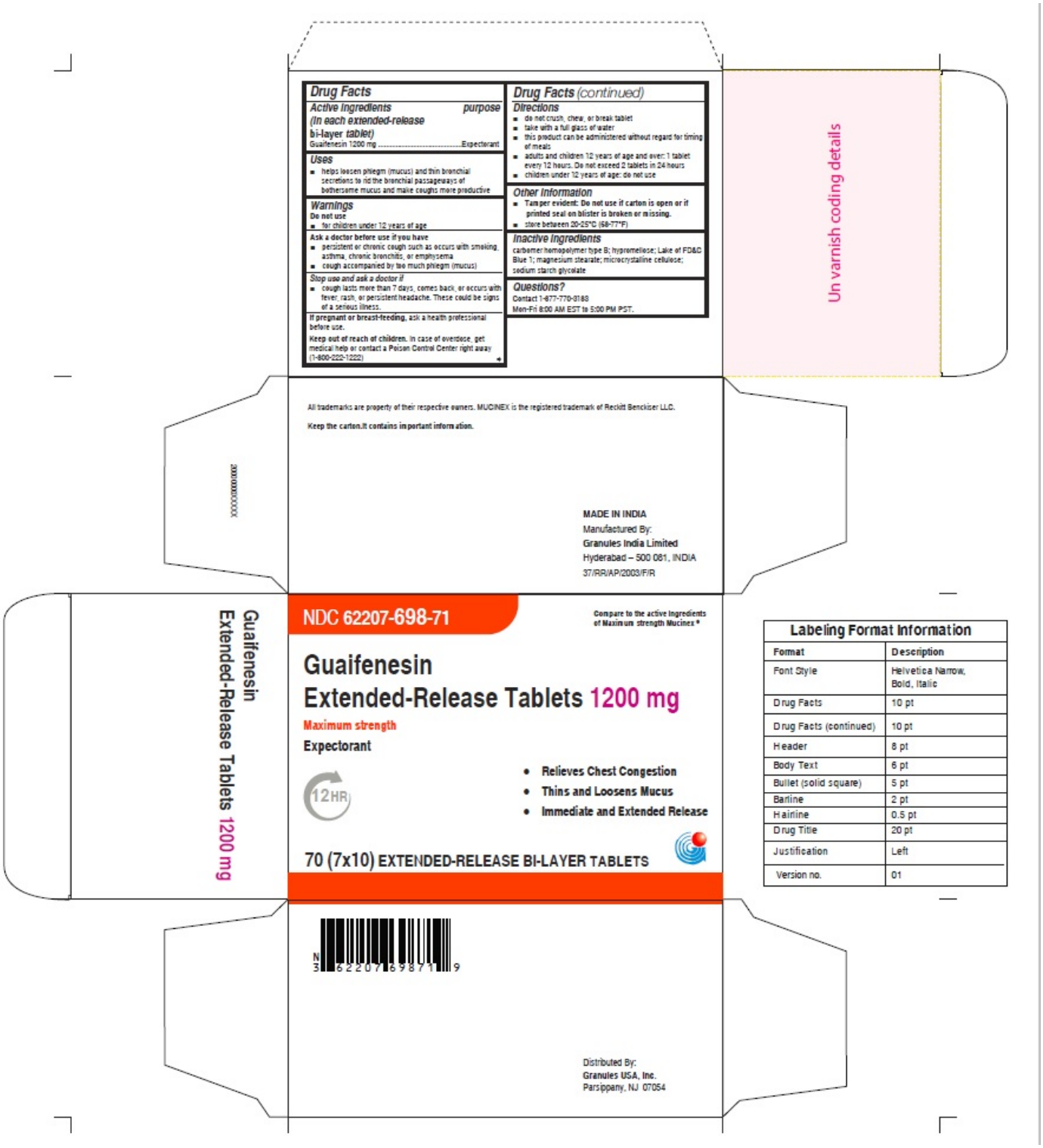
STORAGE

store between 20-25°C (68-77°F)

PRINCIPAL DISPLAY PANEL



Labeling Format Information	
Format	Description
Font Style	Helvetica Narrow, Bold, Italic
Drug Facts	10 pt
Drug Facts (continued)	10 pt
Header	8 pt
Body Text	6 pt
Bullet (solid square)	5 pt
Barline	2 pt
Hairline	0.5 pt
Drug Title	20 pt
Justification	Left
Version no.	01



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Body Text	6 pt
Bullet (solid square)	5 pt
Barline	2 pt
Hairline	0.5 pt
Drug Title	20 pt
Justification	Left
Version no.	01

GUAIFENESIN EXTENDED-RELEASE TABLETS, 600MG

guaifenesin extended-release tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62207-697
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	blue (white and blue)	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	G;600
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:62207-697-72	9 in 1 CARTON	09/10/2020	
1		10 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	ANDA213420	09/10/2020	

GUAIFENSIN EXTENDED-RELEASE TABLETS, 1200 MG

guaifensin extended-release tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62207-698
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
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	blue (white-blue)	**Score**	no score
Shape	OVAL	**Size**	22mm
Flavor		**Imprint Code**	G;1200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-698-71	7 in 1 CARTON	09/10/2020	
1		10 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	ANDA213420	09/10/2020	

Labeler - Granules India Ltd (915000087)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Ltd		918609236	manufacture(62207-697, 62207-698) , analysis(62207-697, 62207-698) , pack(62207-697, 62207-698) , label(62207-697, 62207-698)

Revised: 2/2023 Granules India Ltd