DEROFEN MIEL- guaifenesin .beta.-isomer syrup
Grimann, S.A. de C.V.

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.

DEROFEN MIEL.

DROG DOSAGE INSTRUCTIONS FOR ADMINISTRATION:
Adults and children 12 years and over: 1 tablet a day.

WARNINGS AND PRECAUTIONS: Do not exceed the recommended dosage. If you are taking other medicines, consult your doctor. Do not use loratadine with alcohol or other central nervous system depressants. Children under 12 years old: do not use
PEDIATRIC USE: Children under 12 years of age: do not use.
PREGNANCY AND BREASTFEEDING: Do not use during pregnancy or breastfeeding.
CONTRAINDICATIONS: Do not use in case of hypersensitivity to the ingredients.
ADVERSE REACTIONS: Fatigue, headache, dry mouth, nausea, gastritis, skin rash.
ACCIDENTAL INGESTION AND OVERDOSE: Reported symptoms in case of overdose: sleepiness, tachycardia, headache.
The treatment that should be started immediately is symptomatic and adjuvant. Keep out of reach of children. If symptoms persist for more than 5 days, consult your doctor.
Do not store above 86°F. Keep this container tightly closed.

INACTIVE INGREDIENTES: Magnesium Stearate, Lactose Starch Corn,Water

Therapeutic indications: Indicated for the symptomatic treatment of manifestations related to allergic rhinitis such as:
sneezing, runny nose and watery eyes.
Also indicated for chronic hives and other manifestations of allergic dermatological disorder

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

WARNINGS AND PRECAUTIONS: Do not exceed the recommended dosage. If you are taking other medicines, consult your doctor. Do not use loratadine with alcohol or other central nervous system depressants. Children under 12 years old: do not use
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Do not store above 86°F. Keep this container tightly closed.

PURPOUSE/ USES
Indicated for the symptomatic treatment of manifestations related to allergic rhinitis such as:
- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

FULL PACKAGE

DEROFEN MIEL

guaifenesin .beta.-isomer syrup

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81660-435
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3)	PROPYLENE GLYCOL	11.8 g in 1 U

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	5.9 g in 1 U
HONEY (UNII: Y9H1V576FH)	28.32 g in 1 U
METHYLPARABEN (UNII: A2I8C7HI9T)	0.1 g in 1 U
SUCROSE (UNII: C151H8M554)	53.1 g in 1 U
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.177 g in 1 U
DEUDEXTROMETHORPHAN HYDROBROMIDE (UNII: W9F1OD5N5J)	0.236 g in 1 U
ALCOHOL (UNII: 3K9958V90M)	0.481 mL in 1 U
WATER (UNII: 059QF0KO0R)	118 mL in 1 U
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	0.354 g in 1 U
GUAIFENESIN .BETA.-ISOMER (UNII: 05T4JZ7JLV)	2.36 g in 1 U

Product Characteristics

Color	red	**Score**	no score
Shape		**Size**	10mm
Flavor	RASPBERRY	**Imprint Code**	118
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81660-435-01	1 U in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	05/05/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	05/05/2021	

Labeler - Grimann, S.A. de C.V. (812806982)

Registrant - Grimann, S.A. de C.V. (812806982)

Establishment

Name	Address	ID/FEI	Business Operations
GRIMANN, S.A. de C.V.		812806982	manufacture(81660-435) , label(81660-435)

Revised: 4/2021