GUAIFENESIN SYRUP AND DEXTROMETHORPHAN- guaifenesin syrup and dextromethorphan syrup
Natco Pharma USA LLC

Guaifenesin Syrup and Dextromethorphan

Non-Narcotic - Alcohol Free

DRUG FACTS

Active Ingredient (in each 5 mL cup) **Purpose**

Guaifenesin, USP 100mg ..... Expectorant
Dextromethorphan HBr, USP 10mg ..... Cough Suppressant

Active Ingredient (in each 10 mL cup) **Purpose**

Guaifenesin, USP 200mg ..... Expectorant
Dextromethorphan HBr, USP 20mg .....Cough Suppressant

Inactive Ingredients

Anhydrous citric acid, dextrose, FD&C Red No. 40, flavor, glycerin, high fructose corn syrup, menthol, purified water, saccharin sodium, sodium benzoate.

Uses

• helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive.
• temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold.

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) or for two weeks after stopping the MAOI drug.

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

Ask a doctor or pharmacist before use if you are taking any other drug

Stop use and ask a doctor if

• your cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or

persistant headache.
• you are hypersensitive to any of the ingredients

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 (1-800-222-1222)

DIRECTIONS:

Age	Dose
Adults and children 12 years and over	10 mL every 4 hours Max dose is 60mL in 24-hours
Children under 12 years of age	Ask a doctor

HOW SUPPLIED:

Each 5 mL of Guaifenesin Syrup and Dextromethorphan contains Guaifenesin 100mg and Dextromethorphan Hydrobromide 10mg and is supplied in the following oral dosage forms:

NDC 69339-149-05 (1) unit dose cup 5mL
NDC 69339-149-19 100 (10x10) unit dose cups 5mL

Each 10 mL of Guaifenesin Syrup and Dextromethorphan contains Guaifenesin 200mg and Dextromethorphan Hydrobromide 20mg and is supplied in the following oral dosage forms:

NDC 69339-150-01 (1) unit dose cup 10mL
NDC 69339-150-19 100 (10x10) unit dose cups 10mL

Other Information
• Store at controlled room temperature 20-25ºC (68-77ºF)
• Do not refrigerate
• Keep tightly closed
• Each 5mL contains sodium 3mg
• Each 10mL contains sodium 6mg
• Fruit punch flavor
• Do not use if lid seal is open or damaged
• See top of cup for lot number and expiration date

Questions or comments?
Call 201-786-6500

Dash Pharmaceuticals LLC
Upper Saddle River, NJ 07458

DP-UD-PI-AT-[117893] Rev 08/20

PRINCIPAL DISPLAY PANEL - 5 mL Unit Dose Cup Label

Delivers 5 mL
NDC 69339-149-05

GUAIFENESIN SYRUP &

DEXTROMETHORPHAN HBr

100 mg/10 mg per 5 mL

For Institutional Use Only

3 69339 14905 8

Lot # 111

Exp: 09/22/2020

See Insert

Dash Pharmaceuticals LLC

Upper Saddle River, NJ 07458

DASH-

DOSE

PRINCIPAL DISPLAY PANEL - 10 mL Unit Dose Cup Label

Delivers 10 mL
NDC 69339-150-01

GUAIFENESIN SYRUP &

DEXTROMETHORPHAN HBr

200 mg/20 mg per 10 mL

For Institutional Use Only

3 69339 15001 6

Lot # 111

Exp: 09/22/2020

See Insert

Dash Pharmaceuticals LLC

Upper Saddle River, NJ 07458

DASH-

DOSE

GUAIFENESIN SYRUP AND DEXTROMETHORPHAN

guaifenesin syrup and dextromethorphan syrup

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69339-149
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DEXTROSE (UNII: IY9XDZ35W2)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MENTHOL (UNII: L7T10EIP3A)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics			
Color	red	**Score**	
Shape		**Size**	
Flavor	FRUIT PUNCH	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69339-149-19	10 in 1 CASE	10/19/2020	
1		10 in 1 TRAY		
1	NDC:69339-149-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/19/2020	

GUAIFENESIN SYRUP AND DEXTROMETHORPHAN

guaifenesin syrup and dextromethorphan syrup

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69339-150
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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Inactive Ingredients

Ingredient Name	Strength
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DEXTROSE (UNII: IY9XDZ35W2)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MENTHOL (UNII: L7T10EIP3A)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics

Color	red	**Score**	
Shape		**Size**	
Flavor	FRUIT PUNCH	**Imprint Code**	
Contains			

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69339-150-19	10 in 1 CASE	10/19/2020	
1		10 in 1 TRAY		
1	NDC:69339-150-01	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/19/2020	

Labeler - Natco Pharma USA LLC (079590418)

Revised: 11/2023 Natco Pharma USA LLC