

DEXTROMETHORPHAN HYDROBROMIDE AND GUAIFENESIN-
dextromethorphan hydrobromide and guaifenesin syrup
OPMX LLC

Histiacil NF Children
Pentrexilina NF Children
Brosolvan Children

Active Ingredient (in each 5 mL)	Purpose
Dextromethorphan HBr USP 10 mg.....	Cough suppressant
Guaifenesin, USP 100 mg.....	Expectorant

Relieves:

- Chest congestion / Mucus
- Cough

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps to loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

Warnings

- **Do not use** if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

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

- take every 4 hours
- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- keep dosing cup with product

Age	Dose
Adults and children 12 years and over	2 teaspoonful (10 mL)
Children 6 to under 12 years	1 teaspoonful (5 mL)
Children under 6 years	Ask a doctor

Other information

- Store at 20°-25°C (68° -77°F).
- Do not refrigerate.
- Retain carton for future reference on full labeling

Inactive ingredients

citric acid, flavor, glycerin, menthol, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium saccharin, sorbitol.

Questions or comments?

Call 619-600-5632

Tamper evident: Do not use if inner seal under cap is broken or missing.

Exclusively distributed by

OPMX

Chula Vista, CA91910

Phone: 619-600-5632

Manufactured in

FDA Registered Facility

In the USA

PRINCIPAL DISPLAY PANEL



Brosolvan

NDC 89729-035-04

Dextrometorphan HBr
Guafenesina



sabor Cereza

niños

Soluci n

Alivia:

- Congestion / Flemas
- Tos

Contenido neto 118 mL / 4 FL OZ

Glite - No Coating

Lot No:

Exp. Date:

NON VARNISH AREA



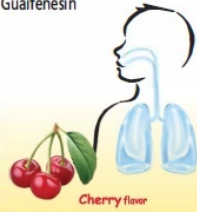
Brosolvan children



Brosolvan

NDC 89729-035-04

Dextromethorphan HBr
Guafenesin



Cherry flavor

children

Cough Syrup

Relieves:

- Chest congestion / Mucus
- Cough

Net Contents 4 FL OZ / 118 mL

Tamper evident: Do not use if inner seal under cap is broken or missing.

Drug Facts

Active Ingredients (in each 5 mL)

Active Ingredient	Purpose
Dextromethorphan HBr	Cough suppressant
USP 10 mg	
Guafenesin, USP 100 mg	Expectorant

Uses

- Temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps to loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease) or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

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.

Drug Facts (continued)

Directions

- take every 4 hours
- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- keep dosing cup with product

AGE	DOSE
Adults and children 12 years and over	2 teaspoonful (10 mL)
Children 6 to under 12 years	1 teaspoonful (5 mL)
Children under 6 years	Ask a doctor

Other information

- Store at 20°-25°C (68°-77°). Do not refrigerate.
- Retain carton for future reference on full labeling.

Inactive ingredients

citric acid, flavor, glycerin, menthol, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium saccharin, sorbitol

Questions or comments?
call 658-600-5622

VERSION EN ESPAÑOL EN EL INTERIOR DE LA CAJA

Manufactured by
OPVIX
Chico, New York, USA
Phone: (518) 392-3333

Made for:
OPVIX
San Diego, CA

Manufactured in
FDA approved facility
in the USA



Glue - No Coating

NDC 69729-036-04

Histiacil^{NF}

Dextromethorphan HBr
Guaifenesin

Cough

Children Syrup

- Helps relieve cough
- Promotes phlegm expulsion
- Helps to decongest the respiratory tract



Administration way:
Oral
Boxed bottle of
4 fl oz
118 mL
and measuring cup

Tamper evident: Do not use if inner seal under cap is broken or missing.

Drug Facts

Active Ingredients (in each 5 mL)	Purpose
Dextromethorphan HBr	Cough suppressant
USP 10 mg	
Guaifenesin USP 100 mg	Expectorant

Uses

- Temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- Helps to loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

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.

NDC 69729-036-04

Histiacil^{NF}

Dextrometorfano HBr
Guaifenesina

Tos

Jarabe Infantil

- Ayuda a calmar la tos
- Facilita la expulsión de flemas
- Promueve la descongestión de las vías respiratorias



Vía de administración:
Oral
Caja con botella de
4 fl oz
118 mL
y copa dosificadora

- Helps relieve cough
- Promotes phlegm expulsion
- Helps to decongest the respiratory tract

Children Syrup

Cough

Dextromethorphan HBr - Guaifenesin

Drug Facts (continued)

Directions

- Take every 4 hours
- Do not take more than 6 doses in any 24-hour period
- Measure only with dosing cup provided
- Keep dosing cup with product

AGE	DOSE
Adults and children 12 years and over	2 teaspoonful (10 mL)
Children 6 to under 12 years	1 teaspoonful (5 mL)
Children under 6 years	Ask a doctor

Other information

- Store at 20°-25°C (68°-77°F)
- Do not refrigerate
- Retain carton for future reference on full labeling

Inactive ingredients

citric acid, flavor, glycerin, menthol, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium saccharin, sorbitol

Questions or comments?

call 619-600-5632

VERSION EN ESPAÑOL EN EL INTERIOR DE LA CAJA

Manufactured by:
OPNIX
Chico, MA, USA
Phone: 619-600-5632

Made for:
RX
San Diego, CA

Manufactured in:
P.O. Box 10000, San Diego, CA 92110



REV. 01/2022
Item # R107093



Lot No.:

Exp. Date:

NON VARNISH AREA



DEXTROMETHORPHAN HYDROBROMIDE AND GUAIFENESIN

dextromethorphan hydrobromide and guaifenesin syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-035
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL

GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)

GUAIFENESIN

100 mg
in 5 mL**Inactive Ingredients**

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-035-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	02/01/2021	

DEXTROMETHORPHAN HYDROBROMIDE AND GUAIFENESIN

dextromethorphan hydrobromide and guaifenesin syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-036
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH)	DEXTROMETHORPHAN	10 mg

(DEXTROMETHORPHAN - UNII:7355X3ROTS)	HYDROBROMIDE	in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-036-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	02/01/2021	

DEXTROMETHORPHAN HYDROBROMIDE AND GUAIFENESIN

dextromethorphan hydrobromide and guaifenesin syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-069
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-069-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	02/01/2021	

Labeler - OPMX LLC (029918743)

Establishment

Name	Address	ID/FEI	Business Operations
Seaway Pharma Inc.		117218785	manufacture(69729-035, 69729-036, 69729-069)