

MIELIM Y MAS- dextromethorphan liquid
Efficient Laboratories Inc.

Drug Facts

Active Ingredient: (In each teaspoonful 5 mls)

Purpose

Dextromethorphan HBr 15 mg (USP).....Cough Suppressant

Cough Suppressant

Warnings

A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash or persistent headache, consult a doctor.

Do not use

- this product for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.
- 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.

Stop use and ask a doctor

- if cough persists for more than 1 week, tends to recur, or is accompanied by a fever, rash or persistent headache.

Keep Out of Reach of Children.

In case of accidental overdose, get medical help or contact the Poison Control Center right away.

If pregnant or breast-feeding,ask a health professional before use.

Directions:

Shake well immediately before use.

Do not exceed 4 doses in any 24 hour period.

Adults and Children 12 years and over - 10 ml (2 tsps) every 6 to 8 hours

Children 6 to under 12 years of age - 5 ml (1 tsp) every 6 to 8 hours

Children under 6 years of age - Consult a doctor

Temporarily relieves cough as may occur with the common cold or inhaled irritants.


Inactive Ingredients: Aspartame, Flavor, Honey, Methylparaben, Potassium Sorbate, Propylene

Glycol, Propylparaben, Purified Water and Sodium Chloride.

Questions or Comments?

305.805.3456 Monday-Friday 9AM to 5PM EST

www.efficientlabs.com

<p>Drug Facts</p> <p>Active ingredient: (in each teaspoonful 5 ml) Purpose Dextromethorphan HBr 15 mg (USP)..... Cough Suppressant</p> <p>Uses • Temporarily relieves cough as may occur with the common cold or inhaled irritants.</p> <p>Warnings A persistent cough may be a sign of a serious conditions. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash or persistent headache, consult a doctor.</p> <p>Do not use</p> <ul style="list-style-type: none"> • this product for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor. • 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. <p>Stop use and ask a doctor If cough persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. ➔</p>	 <p>EFFICIENT LABORATORIES, INC.</p> <h1>Mielim y más®</h1> <p>ANTITUSSIVE ADVANCED FORMULA Dextromethorphan HBr Cough Suppressant Made with PURE HONEY Pleasant LEMON FLAVOR Free of alcohol and antihistamines</p>	<p>Directions: Shake well immediately before each use. Do not exceed 4 doses in any 24 hour period.</p> <table border="1"> <thead> <tr> <th>Age</th> <th>Dose</th> </tr> </thead> <tbody> <tr> <td>Adults and Children 12 years and over</td> <td>10ml (2 tsp) every 6 to 8 hrs.</td> </tr> <tr> <td>Children 6 to under 12 years of age</td> <td>5ml (1 tsp) every 6 to 8 hrs.</td> </tr> <tr> <td>Children under 6 years of age</td> <td>Consult a doctor</td> </tr> </tbody> </table> <p>Other Information Each 5 ml contains: sodium 6 mg, and potassium 2 mg. Phenylketonurics: Contains Phenylalanine 6.75 mg per 5 ml (teaspoonful). Tamper Evident Feature: Do not use if cap seal is torn, broken or missing. Dosage cup included. Store between 15° - 30° C (59° - 86° F). Does not contain alcohol or antihistamines. Product color and flavor may vary due to natural honey.</p> <p>Inactive Ingredients: Aspartame, Flavor, Honey, Methylparaben, Potassium Sorbate, Propylene Glycol, Propylparaben, Purified Water and Sodium Chloride.</p> <p>Questions or Comments? 305.805.3456 Monday- Friday 9 AM to 5PM EST www.efficientlabs.com</p> <p style="text-align: right;">Distributed by Efficient Laboratories, Inc., Miami, FL 33166 Made in U.S.A.</p>	Age	Dose	Adults and Children 12 years and over	10ml (2 tsp) every 6 to 8 hrs.	Children 6 to under 12 years of age	5ml (1 tsp) every 6 to 8 hrs.	Children under 6 years of age	Consult a doctor
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Lot #. _____	Rev 03/17									
Exp. Date: _____	Net Wt. 6 fl. oz. (178 mls.)									

MIELIM Y MAS			
dextromethorphan liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58593-295
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)		DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 5 mL
Inactive Ingredients			
Ingredient Name			Strength
ASPARTAME (UNII: Z0H242BBR1)			
HONEY (UNII: Y9H1V576FH)			
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)			

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

PROPYLPARABEN (UNII: Z8IX2SC1OH)

METHYLPARABEN (UNII: A2I8C7HI9T)

WATER (UNII: 059QF0KO0R)

SODIUM CHLORIDE (UNII: 451W47IQ8X)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58593-295-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/1997	05/16/2023
2	NDC:58593-295-06	178 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/1997	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	02/01/1997	

Labeler - Efficient Laboratories Inc. (969044932)

Registrant - Efficient Laboratories Inc. (969044932)

Establishment

Name	Address	ID/FEI	Business Operations
Dextrum Laboratories Inc.		007392322	manufacture(58593-295)

Revised: 5/2024

Efficient Laboratories Inc.