

**MIELIM Y MAS- dextromethorphan liquid**  
**Efficient Laboratories Inc.**

*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.*

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**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><b>Drug Facts</b></p> <p><b>Active ingredient:</b> (in each teaspoonful 5 ml) <b>Purpose</b> Dextromethorphan HBr 15 mg (USP)..... Cough Suppressant</p> <p><b>Uses</b> • Temporarily relieves cough as may occur with the common cold or inhaled irritants.</p> <p><b>Warnings</b> 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><b>Do not use</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• if you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.</li> </ul> <p><b>Stop use and ask a doctor</b> If cough persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache.</p> <p><b>If pregnant or breast-feeding</b>, ask a health professional before use.</p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away. ➡</p>	 <p><b>EFFICIENT</b> LABORATORIES, INC.</p> <p><b>Mielim y más®</b></p> <p><b>ANTITUSSIVE</b></p> <p><b>ADVANCED FORMULA</b></p> <p><b>Dextromethorphan HBr</b></p> <p><b>Cough Suppressant</b></p> <p><b>Made with PURE HONEY</b></p> <p><b>Pleasant LEMON FLAVOR</b></p> <p><b>Free of alcohol and antihistamines</b></p>	<p><b>Directions:</b> 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 tps) 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><b>Other Information</b> Each 5 ml contains: sodium 6 mg, and potassium 2 mg. Phenylketonurics: Contains Phenylalanine 6.75 mg per 5 ml (teaspoonful). <b>Tamper Evident Feature:</b> 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><b>Inactive Ingredients:</b> Aspartame, Flavor, Honey, Methylparaben, Potassium Sorbate, Propylene Glycol, Propylparaben, Purified Water and Sodium Chloride.</p> <p><b>Questions or Comments?</b> 305.805.3456 Monday- Friday 9 AM to 5PM EST www.efficientlabs.com</p>	Age	Dose	Adults and Children 12 years and over	10ml (2 tps) 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.)**

**Distributed by**  
Efficient Laboratories, Inc., Miami, FL 33166  
Made in U.S.A.

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

Ingredient Name	Strength
<b>ASPARTAME</b> (UNII: Z0H242BBR1)	
<b>HONEY</b> (UNII: Y9H1V576FH)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM CHLORIDE</b> (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 final	part341	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: 5/2023

Efficient Laboratories Inc.