# BISOLVINE CHILD- guaifenes in, dextromethorphan liquid Pharmalab Enterprises 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 Ingredients (in each 5 mL)	Purpose
Guaifenesin 100 mg	Expectorant
Dextromethorphan	Cough Suppressant

#### Uses

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

#### Warnings: Do not exceed recommended dosage.

A persistent or chronic cough may be a sign of a serious condition. If cough persists for more than one 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.

#### Keep out of reach of children

**If pregnant or breast-feeding,** ask a health professional before use. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

#### **Other Information**

#### **Other Information**

• store this product between (15 to 30 C) (59 to 86 C)

### Distributed by Menper Distributors, Inc.

6500 N.W. 35th Ave., Miami, Fl, 33147 www.menperdistributors.com

Directions Directions • Do not exceed 6 doses in 24 hours

Age	Dose
Children 6 to under	1 tablespoonful (15 mL)
12 years of age	every 4 hours
Children 2 to under	1/2 tablespoonful (7.5 mL)
6 years of age	every 4 hours
Children under 2 years of age	Consult your doctor

BISOLVINE GUAIFENESIN, DEXTROMETHORPHAN STRUMERY STRUMERY STRUMERY	Emt) Purpose	Coug	r throat and bronchial irritation helps loosen philogin (mucus) ughs more productive.	isnded dosage. erious condition. It cough o recur, or is accompanied by it a doctor.	ough, such as occurs with ugh is accompanied by et by a doctor, noamine oxidase inhibitor roamine oxidase inhibitor roamine oxidase inhibitor noamine oxidase inhibitor noamine oxidase inhibitor no 2 weeks after strophing the escription drug contains an taking this product.	alth professional before use. edical help or contact a Poison	ses in 24 hours. dose	1 tablespoonful (15 mL) every 4 hours	1/2 tablespoonful (7.5 mL) every 4 hours	consult your doctor	30°C) (59° to 86°F)	i stræwberry-banana tlavor, citric propylene glycol, propylparaben,	
GUAIFENESIN, DEXTROMETHORPHAN Strawberry Browgh Suppressant / Expectoremet For the Temporary Relief of Cough and Congestion due to the Common Cold	Drug Facts	Drug Facts Active Ingredients (in each 15 mL) Guartenesin 100 m0 Dedromethorphan HER 10 mg	Active Ingredients (in each 1 Guatenesin 100 mg Destromethorphan HBR 10 mg	USes Listence and bronchial irritation a temporarily relieves cough due to minor throat and bronchial irritation as may occur with the controon cold and helps loosen phagm (mucus) and thin bronchial secretions to make coughs more productive.	and thin broinchild secretions to make coughs more productive. <b>Warnings D</b> not exceed recommended dosage. Warnings <b>D</b> not exceed recommended dosage. Marnings on the plan sign of a servicus condition. It cough A persistent cough may be a sign of a servicus condition. It cough presists for more than one week, tends to recur, or is accompanied by lever, rash or persistent headache, consult a doctor.	<ul> <li>Do not use:</li> <li>this product for persistent or chronic cough, such as occurs with smoking, astimm, or emphysiems or if cough is accompanied by secretive philegrin (mucula), unless dreated by a doctor, excessive philegrin (mucula), unless dreated by a doctor.</li> <li>if you are now taking a prescription monoamine oxidase inhibitor (MAQI) (cartain drugs for depression, psyciliatric, or emolonal (MAQI) (cartain drugs for depression, psyciliatric, or emolonal MAQI) (cartain drugs for depression, psyciliatric, or emolonal MAQI) as a doctor or pharmacist before taking this product.</li> </ul>	Neep out on recent of the set	Directions - Do not exceed 6 doses in 24 hours	Children 6 to under	12 years of age Children 2 to under	5 years or aye Children under 2 years of age	Other Information store this product between (15° to 30°C) (59° to 86°F)	Inactive Ingredients artiticial strawberry-banana flavor, citrio acid, F.D.& C red #40, methylparaben, propylene glycol, propylparaben purified water, sucrose.

<b>BISOLVINE CHILD</b> guaifenesin, dextromethorphan liqu	ıid				
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (S	ource)	NDC:14505-	488
Route of Administration	ORAL				
Active Ingredient/Active Moi	ety				
Ingre	edient Name		Basis of Str	ength	Strength
DEXTRO METHO RPHAN HYDRO BRO	MIDE (UNII: 9 D2RTI9 KYH)		DEXTROMETHORP	HAN	100 mg

(DEXTROMETHORP	HAN - UNII:7355X3ROTS)	HYDROBRO	MIDE in 5 mL
GUAIFENESIN (UNI	II: 495W7451VQ) (GUAIFENESIN - UNII:495W7	451VQ) GUAIFENES	IN 10 mg in 5 mL
Inactive Ingred	lients		
	Ingredient Name		Strength
	OHYDRATE (UNII: 2968PHW8QP)		
FD&C RED NO.40	(UNII: WZB9127XOA)		
	(UNII: A2I8C7HI9T)		
	C <b>OL</b> (UNII: 6DC9Q167V3)		
	(UNII: Z8IX2SC1OH)		
WATER (UNII: 059C			
SUCROSE (UNII: C1	.51H8 M554)		
<b>Product Charac</b> Color			core
Shape			ize
Flavor	STRAWBERRY (Strawberry -Banana Flavor)	Ь	mprint Code
Contains			
Packaging			
# Item Code	e Package Description	Marketing Start Date	Marketing End Date
1 NDC:14505-488-0	120 mL in 1 BOTTLE, PLASTIC		
Marketing Ir	nformation		
0		h Citation Marketing Start	Date Marketing End Dat
Marketing Catego	ory Application Number of Monograp		
Marketing Catego OTC monograph fina		02/18/2010	

Labeler - Pharmalab Enterprises Inc. (174401088)

Registrant - Pharmalab Enterprises Inc. (174401088)

## Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Pharmalab Enterprises Inc.		174401088	manufacture

Revised: 8/2010

Pharmalab Enterprises Inc.