

DEFENSOL-ITO- dextromethorphan, guaifenesin, phenylephrine solution
Menper Distributors, 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.

Active Ingredient (in each 1 mL, dropperful)	Purpose
Dextromethorphan 4 mg.....	Cough Suppressant
Guaifenesin 50 mg.....	Expectorant
Phenylephrine HCl 2.5mg.....	Nasal Decongestant

Cough Suppressant
Expectorant
Nasal Decongestant

Uses temporarily relieves these symptoms occurring with cold:

- nasal congestion
- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes.

Do not use in child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if your child has

- heart disease
- thyroid disease
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with asthma
- high blood pressure
- diabetes

When using this product, do not use more than directed

Stop use and ask doctor if

- your child gets nervous, dizzy, or sleepless
- symptoms do not get better within 7 days, comes back, or is accompanied by fever
- 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.

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not use more than doses in any 24-hour period
- repeat every 4 hours
- choose dosage by weight (if weight is not known, choose by age)
- measure with the dosing device provided. Do not use with any other device.

Age	Weight	Dose
2 to under 6 years	24-47 Lbs	1 mL
under 2 years	under 24 Lbs	ask as doctor

Drug Facts (continued)

Other information

- store at 20-20 C (68-77 F)
- alcohol-free
- oral dosing device enclosed

Tamper-Evident: Do not use this product if seal on bottle is torn, broken or missing

Questions? call **1-800-560-5223** M-F 9 AM to 4 PM Eastern

Inactive ingredients

citric acid, corn syrup, FD&C yellow #6, flavor, glycerin, guar gum, menthol, methylparaben, propylene glycol, propylparaben, sodium saccharin, sucralose, water

SABOR A FRUTAS **SIN ALCOHOL**

PARA SUS NIÑITOS
DEFENSOL-ITO
SOLUCIÓN

Tos y Catarro

Suprime la Tos/Expectorante/Descongestionante Nasal
Dextrometorfan HBr/Guaifenesina/Fenilefrina HCl

Para Niños de 2 a menores de 6 años de edad

CONTIENE GOTERO ORAL

CONTENIDO: 1 Oz. FL. (30 mL)

FRUIT FLAVOR **ALCOHOL FREE**

FOR YOUR LITTLE CHILDREN
DEFENSOL-ITO
SOLUTION

Cough & Cold

Cough Suppressant/Expectorant/Nasal Decongestant
Dextromethorphan HBr/Guaifenesin/Phenylephrine HCl

For Children 2 to under 6 Years

ORAL DROPPER ENCLOSED

CONTENTS: 1 FL. Oz. (30 mL)

Drug Facts (continued)

Other information

- store at 20-25°C (68-77°F)
- alcohol-free
- oral dosing device enclosed

Inactive ingredients
citric acid, corn syrup, FD&C yellow #6, flavor, glycerin, guar gum, menthol, methylparaben, propylene glycol, propylparaben, sodium saccharin, sucralose, water

Questions? call 1-800-560-5223 M-F 9 AM to 4 PM Eastern.

Tamper-Evident: Do not use this product if imprinted safety seal over bottle cap is torn, broken or missing.

See label for Spanish Drug Facts

Vea la etiqueta para Datos Farmacológicos en español

Defensol-ito Solution is not manufactured by Schering-Plough, S.A. de C.V., (SP MEXICO), owner of the trademark "Desenfrilito"

Distributed by:
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6500 N.W. 35th Avenue
Miami, Florida 33147
www.menperdistributors.com

DEFENSOL-ITO

dextromethorphan, guaifenesin, phenylephrine solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:53145-333

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	4 mg in 1 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	50 mg in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CORN SYRUP (UNII: 9G5L16BK6N)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
GUAR GUM (UNII: E89I1637KE)	
MENTHOL (UNII: L7T10EIP3A)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53145-333-15	1 in 1 CARTON		
1		30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2014	

Labeler - Menper Distributors, Inc (101947166)