

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

Defensol-ito solution

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

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

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 "Desenfriolito"

Distributed by:
Menper Distributors, Inc.
 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		

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:1VS297W6MV)	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)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (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	01/01/2014	
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 Drug	M012	01/01/2014	

Labeler - Menper Distributors, Inc (101947166)

Establishment

Name	Address	ID/FEI	Business Operations
RNV, LLC		118917568	manufacture(53145-333)