

DEFENSOLITO CHILDREN SYRUP- guaifenesin, dextromethorphan hbr liquid
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 ingredients (in each 15mL tsp)

Guaifenesin 100 mg.....Expectorant
Dextromethorphan HBr 10 mg.....Cough suppressant

Purpose

Expectorant
Cough Suppressant

Uses

Temporarily relieves cough due to minor throat and bronchial irritation and nasal congestion as may occur with the common cold and help loosen phlegm (mucus) and thin bronchial secretions to make cough more productive.

Warnings Do not exceed recommended dosage.

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

Do not use:

- in a 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 a pharmacist giving this product.
- this product for persistent or chronic cough such as occur with asthma, or if cough is accompanied ny excessive phlegm (mucus) unless directed by a doctor.

Keep this and all drugs out of the reach of children

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

Directions

do not exceed 6 doses in 24 hours

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

Other information

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

Inactive ingredients

citric acid, D&C red #33, glycerin, methylparaben, natural raspberry flavor, propylene glycol, propylparaben, sucrose and water.

Question?

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

Children
DEFENSOLITO
Cough Syrup

Infantil
DEFENSOLITO
Jarabe Anticatarral

DEXTROMETORFAN HBR
(SUPRESOR DE LA TOS)

GUAIFENESINA
(EXPECTORANTE)

ALIVIA LA:
• Tos

• Congestión del Pecho/Mucosa



Contenido:
4 OZ. FL. (120 mL)

Factores Farmacológicos

Ingredientes activos (en cada 15 mL) **Propósito**
Dextrometorfan HBR 10 mg Supresor de la tos
Guaifenesina 100 mg Expectoante

Usos
■ Alivio temporal de la tos debido a la irritación de la garganta y bronquios, asociada al resfriado común o gripe y ayuda a aliviar la flema (mucosa) y secreciones bronquiales para hacer la tos más productiva.

Advertencias
No exceder la dosis recomendada.
Una tos persistente puede ser señal de una condición seria. Si la tos perdura por más de una semana, regresa o está acompañada por fiebre, dolor de cabeza o erupciones en la piel, consulte a su médico.

No usar
■ en un niño que está tomando ahora alguna medicina bajo prescripción que contenga "MAOI" (ciertas drogas para la depresión, condiciones emocionales, síquicas o enfermedades de Parkinson) o pastillas dos semanas después de haber ingerido medicamentos que contengan MAOI. Si usted no sabe si la prescripción médica de su niño contiene MAOI, consulte a su doctor o a un farmacéutico antes de usarlo.

■ este producto para tos persistente o crónica tal como ocurre si tiene asma, o si la tos es acompañada por flema excesiva (secreción) sólo por indicación médica.

Mantenga este y todos los medicamentos fuera del alcance de los niños.
En caso de sobredosis accidental de este producto, busque ayuda médica o contacte a un Centro de Control de Envenenamiento inmediatamente.

Instrucciones
■ no exceda más de 6 dosis en 24 horas

edad	dosis
Niños de 6 a menores de 12 años	1 cucharada (15 mL) cada 4 horas
Niños de 2 a menores de 6 años	1/2 cucharada (7.5 mL) cada 4 horas
Niños menores de 2 años de edad	consulte a su médico

Otra información
■ conserve este producto entre 15° a 30°C (59° a 86°F)

Ingredientes inactivos
ácido cítrico, DAC rojo #33, glicerina, metilparabeno, sabor natural a fresas, propilenglicol, propilparabeno, sucrosa y agua.

Preguntas? llame 1-800-560-3223 L-V 9 AM a 4 PM Este

Evidencia de Seguridad: No usar si el sello de seguridad impreso sobre la tapa de la botella está torcido, roto, o falta.

Children
DEFENSOLITO
Cough Syrup

DEXTROMETHORPHAN HBR
(COUGH SUPPRESSANT)

GUAIFENESIN
(EXPECTORANT)

RELIEVES:
• Cough

• Chest Congestion/Mucosa



Contents:
4 FL. OZ. (120 mL)

Drug Facts

Active ingredients (in each 15 mL) **Purpose**
Dextromethorphan HBR 10 mg Cough suppressant
Guaifenesin 100 mg Expectorant

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 cough more productive.

Warnings
Do not exceed recommended dosage.
A persistent 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
■ in a 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.

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

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

Directions
■ do not exceed 6 doses in 24 hours

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

Other information
■ store this product between 15° to 30°C (59° to 86°F)

Inactive ingredients
citric acid, DAC red #33, glycerin, methylparaben, natural raspberry flavor, propylene glycol, propylparaben, sucrose and water.

Questions? call 1-800-560-3223 M-F 9 AM to 4 PM Eastern

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

Distributed by:
Menper Distributors, Inc.
11421 N.W. 107 Street, Suite #24, Miami, FL 33178
www.menperdistributors.com



DEFENSOLITO CHILDREN SYRUP

guaifenesin, dextromethorphan hbr liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53145-008
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
RASPBERRY (UNII: 4N14V5R27W)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53145-008-04	1 in 1 CARTON	02/21/2012	
1		120 mL in 1 BOTTLE; 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	02/21/2012	

Labeler - Menper Distributors, Inc. (101947166)

Revised: 2/2022

Menper Distributors, Inc.