

**XPECTO SOOTHING RELIEF- dextromethorphan hbr guaifenesin phenylephrine hcl syrup
MIDWAY IMPORTING 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.

Drug Facts

Active ingredient (in each 10 mL)

Dextromethorphan HBr 20 mg

Guaifenesin 200 mg

Phenylephrine HCl 10 mg

Purposes

Cough suppressant

Expectorant

Nasal Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
- temporarily relieves these symptoms occurring with a cold
- nasal congestion
- cough due to minor throat and bronchial irritation

Warnings

Do not use • 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.

Ask a doctor before use if you have

- trouble urinating due to enlarged prostate gland
- high blood pressure
- thyroid disease • heart disease • diabetes
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema

Ask a doctor or pharmacist before use if you are

taking any other oral nasal decongestant or stimulant

When using this product

do not use more than directed

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not get better within 7 days or are 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

If pregnant or breast-feeding

ask a health professional before

Keep out of reach of children

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

Directions

- shake well before using
- do not take more than 4 doses in any 24-hour period
- measure only with dosing cup provided
- keep dosing cup with product mL=milliliter
- this adult product is not intended for use in children under 12 years of age
- adults and children 12 years and over: 10mL every 4 hours
- children under 12 years: do not use

Other information

- store at 20C-25C (68F-77F). Do not refrigerate

Inactive ingredients

anhydrous citric acid,FD&C Red #40, flavor, glycerin, lactic acid, menthol, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose

Questions or comments?

Call 703-802-9363

Package Label

Drug Facts (continued)
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 • store at 20-25°C (68-77°F). Do not refrigerate.
Inactive ingredients anhydrous citric acid, FD&C red #40, flavor, glycerin, lactic acid, menthol, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose
Questions or comments?
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Información del Medicamento
Ingredientes activos (en cada 10 mL) Propósitos
 Dextrometorfano Hbr 20 mg.....Supresor de tos
 Guaifenesina 200 mg.....Expectorante
 Fenilefrina HCl 10 mg.....Descongestionante nasal
Usos
 • ayuda a desprender la flema (mucosidad) y adelgazar las secreciones bronquiales para drenar los tubos bronquiales
 • alivia temporalmente los siguientes síntomas que se presentan con el resfriado
 • congestión nasal
 • tos debida a irritación menor de garganta y bronquios

Advertencias
 No utilizarlo • si usted está tomando un inhibidor de la monoamino oxidasa (MAOI) por prescripción (ciertos medicamentos para la depresión, condiciones psiquiátricas, o emocionales, o enfermedad de Parkinson), o durante 2 semanas después de suspender el medicamento MAOI. Si usted desconoce si su medicamento de prescripción contiene un MAOI, consulte a su médico o farmacéutico antes de tomar este producto.
 Consulte a su médico si usted padece
 • enfermedad cardíaca
 • hipertensión • enfermedad de la tiroides • diabetes
 • problemas al orinar debido a la dilatación de la glándula prostática
 • tos que se presenta con exceso de flema (mucosidad)
 • tos persistente o crónica tal como ocurre con el tabaquismo, asma, bronquitis crónica o enfisema

Consulte a su médico o farmacéutico antes de utilizarlo si usted está tomando cualquier otro descongestionante o estimulante nasal oral.
 Cuando use este producto, no utilice más de lo indicado.
 Suspénda su uso y consulte a su médico si
 • nerviosismo, mareo, o insomnio ocurren

Información del Medicamento (continuación)
 • si los síntomas no mejoran dentro de 7 días o se acompañan de fiebre
 • la tos persiste por más de 7 días, regresa, o se presenta o si está acompañada por fiebre, erupción, o dolor de cabeza persistente. Estos podrían ser signos de una condición seria.
 En caso de embarazo o lactancia, consulte a un profesional de la salud antes de su uso.
 Manténgase fuera del alcance de los niños. En caso de sobredosis, obtenga ayuda médica o contacte al Centro de Control de Envenenamiento de manera inmediata.

Indicaciones
 • agite bien antes de usar
 • no tomar más de 6 dosis en un periodo de 24 horas
 • use solamente con la tapa dosificadora
 • mantenga la tapa dosificadora con el producto • mL = mililitro
 • este producto de concentración para adultos no está previsto para su uso en niños menores de 12 años de edad
 • adultos y niños de 12 años y mayores: 10 mL cada 4 horas
 • niños menores de 12 años: no utilizar

Información adicional
 • almacenar entre 20-25°C (68-77°F). No refrigerar.

Ingredientes Inactivos ácido anhidro cítrico, ácido láctico, agua purificada, benzoato de sodio, citrato de sodio, FD&C rojo #40, glicerina, mentol, propileno glicol, sorbitol, sucralosa

¿Preguntas o comentarios? Llamar al Tel: (713) 802-9363

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.
 NO USE SI EL SELLO DE SEGURIDAD IMPRESO DEBAJO DE LA TAPA ESTA ROTO O FALTA.



Manufactured for / Fabricado para:
 Broncolin, S.A. de C.V.
 Distributed by / Distribuido por:
 Midway Importing, Inc.
 1807 Brittmoore Road Houston, Texas 77043

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 Guaifenesin 200 mg.....Expectorant
 Phenylephrine HCl 10 mg.....Nasal decongestant
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Cough Suppressant
Antitusivo
Expectorant
Nasal Decongestant
Descongestionante Nasal
 4 FL OZ (118mL)
 Dextromethorphan HBr
 Dextrometorfano Hbr
 Guaifenesin
 Guaifenesina
 Phenylephrine HCl
 Fenilefrina HCl



XPECTO SOOTHING RELIEF
 dextromethorphan hbr guaifenesin phenylephrine hcl syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76095-005	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)		GUAIFENESIN	200 mg in 10 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	10 mg in 10 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)		DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 10 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
SORBITOL (UNII: 506T60A25R)				
GLYCERIN (UNII: PDC6A3C0OX)				
LACTIC ACID (UNII: 33X04XA5AT)				
MENTHOL (UNII: L7T10EIP3A)				
PROPANEDIOL (UNII: 5965N8W85T)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
Product Characteristics				
Color	red (Cherry Red)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76095-005-14	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2016	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	05/09/2016		

Labeler - MIDWAY IMPORTING INC (611851627)