

**LEADER INTENSE COUGH RELIEVER - dextromethorphan hydrobromide /
guaifenesin liquid
Cardinal Health**

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 per 5ml teaspoon

Dextromethorphan Hydrobromide 20mg Cough Suppressant

Guaifenesin 300mg Expectorant

Uses. temporarily relieves cough due to minor throat and bronchial irritation as may occur with a common cold • helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus
• helps make coughs more productive

Do not use if you are now taking a prescription monoamine oxidase (inhiMor~MAIO)

Certain drugs for depression, psychiatric or emotional conditioners or Parkinson's disease

or for 2 weeks after stopping MAIO drug, If you do not know if your prescription drug contains an MAIO, ask your doctor or pharmacist before using this product

Ask doctor before use if you have

persistent or chronic cough, such as occurs with smoking, asthma, bronchitis or emphysema

cough is accompanied by excessive phlegm (mucous)

Stop use and ask doctor if

Symptoms are accompanied by fever, rash or persistent headache

cough persists for more than 1 week or tends to recur

A persistent cough may be a sign of a serious condition

If pregnant or breastfeeding, ask a health professional before use

Keep out of reach of children, In case of overdose, get medical help or contact a Poison Center immediately

Directions

- Adults and children 12 years of age and over:
take 1 tablet every 4 hours as needed
- Children 6 to 10 under 12 years of age: take 1/2 tablet every 4 hours as needed
- Children under 6 years of age: consult a doctor

Do not exceed 6 doses in a 24 hour period or as directed by a doctor

Other information store at 15'- 30' C (59'- 86'F)

Purpose

Dextromethorphan Hydrobromide Cough Suppressant

Guaifenesin

Expectorant

Cherry Flavor, Citric Acid, Menthol, Polyethylene Glycol, Propylene Glycol, Purified Water,

Sodium Benzoate, Sodium Saccharin, Sorbitol.

CAUTION: DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING.

Drug Facts

Active ingredients	Purpose
Dextromethorphan HBr 20mg.....Cough Suppressant	
Guaifenesin 300mg.....Expectorant	

Uses

- Temporarily relieves cough due to minor throat and bronchial irritation as may occur with a common cold
- Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus.
- Helps make coughs more productive.

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 a MAOI, ask a doctor or pharmacist before using this product.

Ask a doctor before use if you have

- persistent or chronic cough, such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough is accompanied by excessive phlegm (mucus).

Stop use and ask a doctor if

- symptoms are accompanied by fever, rash, or persistent headache
- cough persists for more than 1 week or tends to recur

A persistent cough may be a sign of a serious condition.

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately.

Directions

- Adults and children 12 years of age and over take 1 teaspoon every 4 hours as needed
- Children 6 to under 12 years take 1/2 teaspoon every 4 hours as needed
- Children under 6 consult a doctor

Do not exceed 6 doses in a 24 hour period or as directed by a doctor.

Other information

- store between 15°-30° C (59°-86°F)

Inactive ingredients Cherry Flavor, Citric Acid, Menthol, Polyethylene Glycol, Propylene Glycol, Purified Water, Sodium Benzoate, Sodium Saccharin, Sorbitol.

PRECAUCIÓN: NO LO USE SI EL SELLO IMPRESO BAJO LA TAPA ESTÁ ROTO O AUSENTE.

Hechos Acerca Del Medicamento

Ingredientes activos	Propósito
Bronhidrato de dextrometorfano 20mg..... Supresor de la tos	
Guaifenesina 300mg.....Expectorante	

Usos

- Ayuda a aflojar la flema (mucosidad) a afinar las secreciones bronquiales para liberar las vías bronquiales de la molesta mucosidad
- hacer que la tos sea más productiva
- Alivia temporariamente la tos producida por resfriados comunes.

Advertencias

No tome

- este producto si actualmente está tomando medicamentos de prescripción que contienen el inhibidor de Oxidasa Monoamina (MAOI) (ciertos medicamentos para la depresión, estados psiquiátricos o emocionales o Mal de Parkinson), o durante las 2 semanas siguientes a haber dejado de tomar un medicamento con MAOI, consulte a un profesional de la salud.

Consulte a un médico antes de usarlo si tiene

- la tos persistente o crónica como la que ocurre al fumar, con el asma, bronquitis crónica o enfisema
- la tos se acompaña de flema excesiva (moco)

Deje de tomar y consulte a su médico

- los síntomas se acompañan de fiebre, erupción cutánea o dolor de cabeza persistente
- la tos persiste por más de 1 semana o tiende a reaparecer.

Una tos persistente pueda ser signo de un trastorno serio.

Si está embarazada o dando pecho, consulte a un profesional de salud antes de tomar este medicamento. Manténgalo lejos del alcance de los niños. En caso de una sobredosis, consiga asistencia médica inmediatamente.

MAS FUERTE QUE LAS MARCAS PRINCIPALES

Hechos Acerca Del Medicamento (cont.)

Instrucciones

- Adultos y niños mayores de 12 años tome 1 cucharadita cada 4 horas como sea necesario.
- Niños de 6 a 12 años tome 1/2 cucharadita cada 4 horas como sea necesario.
- Niños menores de 6 años consulte a su Médico como sea necesario.

No exceda más de 6 dosis durante un periodo de 24 horas o como se lo indique su Médico.

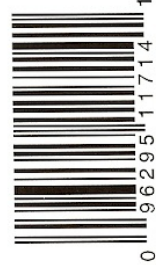
Otra Información

- Guarde a la temperatura ambiente de 15°-30°C (59°-86°F)

Ingredientes inactivos Sabor de cherry, Ácido cítrico, mentol, polietilenglicol, propilenglicol, agua purificada, benzoato sódico, sacarinato sódico, sorbitol.

Distributed By: Cardinal Health
Dublin, Ohio 43017
www.myleader.com
1-800-200-6313
CIN 4219846

All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.



NDC 37205-610-26

LEADER®

EXTRA STRENGTH

Intense Cough Reliever

Dextromethorphan HBr 20mg
Guaifenesin 300mg

Cough Suppressant Expectorant

Sugar Free, Alcohol Free
Non-Drowsy
New Formula

4 Fl Oz (120mL)

LEADER INTENSE COUGH RELIEVER

dextromethorphan hydrobromide / guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-610
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 5 mL	
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	300 mg in 5 mL	
Inactive Ingredients			
Ingredient Name	Strength		
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)			

SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
MENTHOL (UNII: L7T10EP3A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-610-01	1 in 1 CARTON		
1	NDC:37205-610-26	120 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/02/2011	

Labeler - Cardinal Health (097537435)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment			
Name	Address	ID/FEI	Business Operations
Reese Pharmaceutical Co		004172052	relabel, repack