

LEADER CHEST CONGESTION RELIEF PLUS DMDM DM- dextromethorphan hydrobromide / guaifenesin tablet

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 tablet)

Dextromethorphan Hydrobromide 20mg

Guaifenesin 400mg

Purpose

Cough Suppressant

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~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 (mucus)

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 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 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)

Inactive Ingredients magnesium stearate, microcrystalline cellulose. May also contain (colloidal) silicon dioxide, (co) povidone, dicalcium phosphate, maltodextrin, sodium starch glycolate, stearic acid.

Drug Facts (continued)

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 that 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 and over: take 1 tablet every 4 hours as needed.
- children 6 to under 12 years: take 1/2 tablet every 4 hours as needed.
- children under 6 years: 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)

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NDC 37205-538-71



Alivio Para la Congestión del Pecho Plus DM

Guaifenesina 400mg | Dextrometorphan HBr 20mg

**Expectorante
Eliminador de la Tos**

Aloja y alivia la congestión de pecho
Hace la tos más productiva
Controla la tos
Tabletas de efecto inmediato
Sin tinte



50 TABLETOS

Hechos acerca del Medicamento (cont.)

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 puede 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.

Instrucciones

- adultos y niños mayores de 12 años: tome 1 tableta cada 4 horas como sea necesario
- niños de 6 a 12 años: tome 1/2 tableta cada 4 horas como sea necesario
- niños menores de 6 años: consulte a un doctor

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

Otra información guárdalo de 15°-30°C (59°-86°F)

Ingredientes Inactivos estearato de magnesio, celulosa micro cristalina. También puede contener dióxido de silicio (coloidal) (co) povidona, fosfato dicalcico, maltodextrina, Glicolato de almidón sódico, ácido estearico. Rev 9/09 RCLLOR

Drug Facts

Active ingredients (per tablet)

Dextromethorphan HBr 20mg	Cough Suppressant
Guaifenesin 400mg	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.

NDC 37205-538-71



Chest Congestion Relief Plus DM

Guaifenesin 400mg | Dextromethorphan HBr 20mg

**Expectorant
Cough Suppressant**

Loosens & Relieves Chest Congestion
Makes Coughs More Productive
Controls Cough
Immediate Release Tablets
Dye-free



50 TABLETS

Hechos acerca del Medicamento (cont.)

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 puede 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.

Instrucciones

- adultos y niños mayores de 12 años: tome 1 tableta cada 4 horas como sea necesario
- niños de 6 a 12 años: tome 1/2 tableta cada 4 horas como sea necesario
- niños menores de 6 años: consulte a un doctor

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

Otra información guárdalo de 15°-30°C (59°-86°F)

Ingredientes Inactivos estearato de magnesio, celulosa micro cristalina. También puede contener dióxido de silicio (coloidal) (co) povidona, fosfato dicalcico, maltodextrina, Glicolato de almidón sódico, ácido estearico. Rev 9/09 RCLLOR

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LEADER CHEST CONGESTION RELIEF PLUS DMDM DM

dextromethorphan hydrobromide / guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-538
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	400 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OPIR32D61U)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	2 pieces
Shape	OVAL	Size	17mm
Flavor		Imprint Code	PH073
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-538-71	50 in 1 BOTTLE, PLASTIC		
2	NDC:37205-538-01	1 in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/20/2006	

Labeler - Cardinal Health (097537435)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment

Name	Address	ID/FEI	Business Operations
Reese Pharmaceutical Co		004172052	relabel(37205-538) , repack(37205-538)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest		557054835	manufacture(37205-538)