

ROMPE PECHO CF- dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid
Efficient Laboratories 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 Ingredients :(in each teaspoonful 5 ml.)	Purpose
Dextromethorphan HBr 10 mg	Cough Suppressant
Guaifenesin 100 mg	Expectorant
Phenylephrine HCL 5 mg	Nasal Decongestant

Purpose

Cough Suppressant
Expectorant
Nasal Decongestant

Warnings

Do not exceed recommended dosage.

Do not use

- If you are 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 your doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- a persistent or chronic cough
 - a cough that is accompanied by excessive phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema.

Stop use and ask doctor if

- symptoms do not improve within 7 days or is accompanied by a fever, rash, or persistent headache. A persistent cough may be sign of a serious condition.
- nervousness, dizziness, or sleeplessness occurs

If pregnant or breast-feeding, ask a health professional before use.

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

Directions

Shake well before use

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

Age	Dose
adults and children 12 years of age and over	10 mL (2 tsps) every 4 hours
children 6 to under 12 years of age	5 mL (1 tsp) every 4 hours
children under 6 years of age	consult a doctor

Uses

- temporarily relieves cough and nasal congestion as may occur with the common cold
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus.

Inactive Ingredients:Blue Cohosh root extract, Echinacea root extract, Eucalyptus Oil, Ginkgo Biloba leaf extract, glycerin, Golden Seal root extract, Honey, Horehound, Licorice Root extract, Menthol, Methylparaben, Mullein leaf extract, Myrrh gum extract, Potassium Sorbate, Propylene Glycol, Propylparaben, Slippery Elm Bark extract, Sodium Chloride, Sucralose, Water, Wild Cherry Bark extract and Zinc Sulfate.

Questions or Comments?

305-805-3456 Monday - Friday 9AM to 5PM EST

www.efficientlabs.com

Distributed by

Efficient Laboratories, Inc., Miami, Fl 33166

Made in U.S.A.

CF Cold & Flu

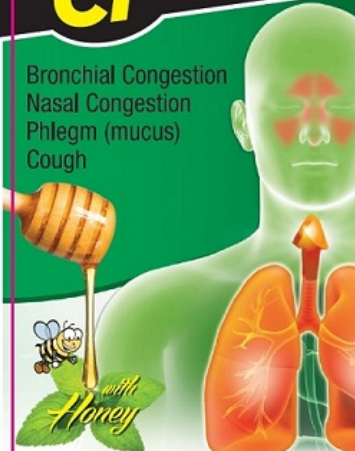
Rompe Pecho®

EFFICIENT NEW PACKAGING!

Rompe Pecho®

CF Cold & Flu

Bronchial Congestion
Nasal Congestion
Phlegm (mucus)
Cough



ALCOHOL FREE

Echinacea, Eucalyptus, Menthol & more
Dextromethorphan HBr (Antitussive)
Guaifenesin (Expectorant)
Phenylephrine HCl (Nasal Decongestant)
NET WEIGHT: 6 FL Oz (178 mL)



Drug Facts

Active ingredients (in each teaspoonful, 5 mL) **Purpose**
Dextromethorphan HBR 10 mg.....Cough suppressant
Guaifenesin 100 mg.....Expectorant
Phenylephrine HCl 5mg.....Nasal decongestant

Uses • temporarily relieves cough and nasal congestion as may occur with the common cold • helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus

Warnings

Do not exceed recommended dosage.

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 • heart disease • high blood pressure • thyroid disease • diabetes • trouble urinating due to enlargement of the prostate gland • a persistent or chronic cough • a cough that is accompanied by excessive phlegm (mucus) • a breathing problem such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Stop use and ask a doctor if • if symptoms do not improve within 7 days or are accompanied by a fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition. • nervousness, dizziness, or sleeplessness occurs

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

Directions

• shake well before use. • do not exceed more than 6 doses in any 24-hour period or as directed by a doctor.

Age	Dose
adults and children 12 years of age and over	10 mL (2 tsp) every 4 hours
children 6 to under 12 years of age	5 mL (1 tsp) every 4 hours
children under 6 years of age	consult a doctor

Other information • dosage cap included • product color & flavor may vary due to natural honey • store between 15°-30° C (59°-86° F)

TAMPER-EVIDENT FEATURE: Do not use this product if printed seal over cap is torn, broken or missing.

Inactive ingredients blue cohosh root extract, echinacea root extract, eucalyptus oil, ginkgo biloba leaf extract, glycerin, goldenseal root extract, honey, honeysuckle, licorice root extract, menthol, methylparaben, milkem leaf extract, myrrh gum extract, potassium sorbate, propylene glycol, propylparaben, slippery elm bark extract, sodium chloride, sucralose, water, wild cherry bark extract and zinc sulfate.

Questions or Comments? 305-605-3456

Monday - Friday (9 AM - 5 PM EST) or www.efficientlabs.com

Other cold formulas: Rompe Pecho® Regular, Rompe Pecho® DM, Rompe Pecho® SF, Rompe Pecho® FLU, Cough Outfit and Maltin & Maltin

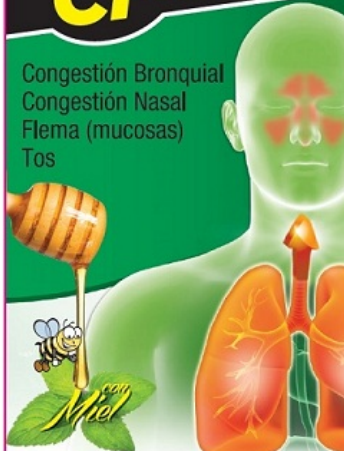
Distributed by:
Efficient Laboratories, Inc.
Miami, FL 33166, Made in U.S.A.

EFFICIENT NUEVO EMPAQUE!

Rompe Pecho®

CF Catarro y Gripe

Congestión Bronquial
Congestión Nasal
Flema (mucosas)
Tos



SIN ALCOHOL

Equinácea, Eucalipto, Mentol y más
Dextrometorfano HBr (Antitussivo)
Guaifenesina (Expectorante)
Fenilefrina HCl (Descongestionante Nasal)
PESO NETO: 6 Oz FL (178 mL)

Datos Farmacológicos

Ingredientes activos (en cada cucharada, 5 mL.) **Propósito**
Dextrometorfano HBr 10 mg.....Supresor de la tos
Guaifenesina 100 mg.....Expectorante
Fenilefrina HCl 5 mg.....Descongestionante nasal

Usos • alivia temporalmente la tos y la congestión nasal producto del resfriado común • ayuda a aliviar la flema (mucosidad) y de esa forma facilita la eliminación de la mucosidad de los conductos bronquiales

Advertencias

No exceda la dosis recomendada.

No utilice • si está tomando un inhibidor de la monoamino oxidasa prescripción (MAOI) (ciertos medicamentos para la depresión, trastornos psiquiátricos o emocionales, o la enfermedad de Parkinson), o durante 2 semanas después de dejar de tomar el MAOI. Si usted no sabe si su medicamento recetado contiene un MAOI, consulta a tu médico o farmacéutico antes de tomar este producto.

Pregúntele a su médico antes de usar si usted tiene • enfermedad cardíaca • alta presión sanguínea • enfermedad tiroidea • diabetes • dificultad para orinar debido al agrandamiento de la glándula de la próstata • una tos persistente o crónica • una tos que se acompaña de flema excesiva (mucosidad) • un problema respiratorio, como ocurre con el tabaquismo, el asma, bronquitis crónica o enfisema

Pare de usar y consulte al médico si los síntomas no mejoran dentro de 7 días o se acompañan de fiebre, erupción cutánea o dolor de cabeza persistente. Una tos persistente puede ser un signo de una enfermedad grave. • Si se produce nerviosismo, mareos o falta de sueño

Si usted está embarazada o lactando pregúntele a un profesional de la salud antes de usar.

Mantener fuera del alcance de los niños. En caso de sobredosis accidental, busque ayuda médica o contacte un Centro de Control de Intoxicación inmediatamente.

Indicaciones

• agitar bien antes de usar • No exceder más de 6 dosis en un periodo de 24 horas o como lo indique un médico

Edad	Dosis
adultos y niños 12 años y más	10 mL (2 cucharaditas) cada 4 horas
niños de 6 años a menores de 12 años	5 mL (1 cucharadita) cada 4 horas
niños menores de 6 años	consulten a un médico

Otra información

• copa de dosis incluida • color y sabor del producto puede variar debido a la miel • almacenar entre 15°-30° C (59°-86° F)

EVIDENCIA DE SEGURIDAD: No utilice este producto si el sello de seguridad impreso sobre la tapa está rasgado, roto o falta.

Ingredientes inactivos extracto de raíz de cohosh azul, extracto de raíz de equinácea, aceite de eucalipto, extracto de hoja de ginkgo biloba, glicerina, raíz de sello dorado, miel, herba marrubio, raíz de regaliz, cristales de mentol, metilparabeno, extracto de hojas de gordolobo, mirra extracto de goma, sorbato de potasio, Propilenglicol, propilparabeno, extracto de corteza de alno resbaladizo, cloruro de sodio, sucralosa, agua, extracto de corteza de cereza salvaje y sulfato de zinc.

¿Preguntas o Comentarios? 305-605-3456

Lunes - Viernes (9 AM - 5 PM EST) o www.efficientlabs.com

Otros fórmulas: Rompe Pecho® Regular, Rompe Pecho® DM, Rompe Pecho® SF, Rompe Pecho® FLU, Cough Outfit and Maltin & Maltin

Distribuido por:
Efficient Laboratories, Inc.
Miami, FL 33166, Hecho en EE.UU.



REV: 02/17
835156-03

Drug Facts (Continued)
 bronchitis, or emphysema
 Stop use and ask a doctor if: symptoms do not improve within 7 days or are accompanied by a fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.
 *menstruation, dizziness, or sleepiness occur.
 If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of an overdose, get medical help or contact a Poison Control Center right away.

Directions
 • shake well before use. • do not exceed more than 6 doses in any 24-hour period or as directed by a doctor.

Age	Dose
Adults and children 12 years of age and over	10 mL (2 tsp) every 4 hours
Children 6 to 11 years of age	5 mL (1 tsp) every 4 hours
Children under 6 years of age	consult a doctor

Other information • dosage cup included • product color & flavor may vary due to natural honey • store between 15°-30° C (59°-86° F)
TAMPER-EVIDENT FEATURE: Do not use this product if printed seal over cap is torn, broken or missing.

Inactive ingredients • hawthorn root extract, echinacea root extract, eucalyptus oil, ginkgo biloba leaf extract, glycerin, goldenseal root extract, honey, horseradish, licorice root extract, menthol, methylphenidol, mullein leaf extract, myrrh gum extract, potassium sorbate, propylene glycol, propylparaben, slippery elm bark extract, sodium citrate, sorbitol, water, wild cherry bark extract and zinc sulfate.

Questions or Comments? 305-865-3466
 Monday - Friday 9 AM - 5 PM EST or www.efficient.com

Over-the-Counter: Rompe Pecho CF Cold & Flu, Rompe Pecho CF Catarro y Gripe, Rompe Pecho CF. Distributed by: Efficient Laboratories, Inc. Miami, FL 33166. Made in U.S.A.

66% more Free
 4 fl oz Bottle Free

BONUS PACK
 66% more Free
 66% más gratis
 4 fl oz Bottle Free/Botella de 4 fl oz gratis

66% más gratis
 Botella de 4 fl oz gratis

Rompe Pecho®
CF Cold & Flu

- Bronchial Congestion
- Nasal Congestion
- Phlegm (mucus)
- Cough

Advanced Formula for your Cold

Rompe Pecho®
CF Cold & Flu

Bronchial Congestion
 Nasal Congestion
 Phlegm (mucus)
 Cough

ALCOHOL FREE
ADVANCED FORMULA
Dextromethorphan HBr (Asthma)
 Guaifenesin (Expectorant)
 Phenylephrine HCl (Nasal Decongestant)

NET WEIGHT: 6 fl oz (178 mL) + 4 fl oz (118 mL) MORE FREE
 TOTAL: 10 fl oz (296 mL)

Rompe Pecho®
CF Catarro y Gripe

- Congestión Bronquial
- Congestión Nasal
- Flema (mocos)
- Tos

Fórmula Avanzada para su Catarro



Rev: 07/18

ROMPE PECHO CF

dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58593-235
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
SUCRALOSE (UNII: 96K6UQ3ZD4)	
HOREHO UND (UNII: K08036XEJV)	
CAULOPHYLLUM THALICTROIDES ROOT (UNII: JTJ6HH6YEH)	
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
GINKGO (UNII: 19FUJ2C58T)	
GOLDENSEAL (UNII: ZW3Z11D0JV)	
HONEY (UNII: Y9H1V576FH)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
MENTHOL (UNII: L7T10EIP3A)	

METHYL PARABEN (UNII: A2I8C7H9T)	
VERBASCUM DENSIFLORUM LEAF (UNII: 9936O846LI)	
MYRRH (UNII: JC71GJ1F3L)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
ULMUS RUBRA BARK (UNII: 91QY4PXU8Q)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PRUNUS SEROTINA BARK (UNII: 5D48E975HA)	
ZINC SULFATE (UNII: 89DS0H96TB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58593-235-06	178 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2007	
2	NDC:58593-235-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2015	
3	NDC:58593-235-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2015	
4	NDC:58593-235-29	296 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	01/01/2015	
5	NDC:58593-235-10	10 mL in 1 POUCH; Type 0: Not a Combination Product	01/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/01/2007	

Labeler - Efficient Laboratories Inc (969044932)

Registrant - Efficient Laboratories Inc (969044932)