

ROMPE PECHITO DM FOR KIDS- dextromethorphan hbr, guaifenesin liquid
Efficient Laboratories Inc

Rompe Pechito

Active Ingredients:(in each teaspoonful 2.5 ml.) **Purpose**

Dextromethorphan Hydrobromide 5 mg Cough Suppressant
Guaifenesin 50 mg Expectorant

Purpose

Cough Suppressant
Expectorant

Uses

Uses:

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes.

Warnings

Do not use in child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional condition, 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.

Do not use

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Keep out of reach of children.

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

Directions

Do not give more than 6 doses in any 24 hours period □ **shake well before use** □ **measure only with dosing cup provided** □ **keep dosing cup with product**
□ mL = milliliter

Age Dose

Children 6 to under 12 years of age 5 mL every 4 hours

Children 4 to under 6 years of age 2.5 mL every 4 hours

Children under 4 years of age Do not use

Inactive Ingredients:

Inactive Ingredients: citric acid, elderberry fruit extract, glycerin, honey, maltodextrin, methylparaben, flavor, potassium sorbate as a preservative, propylparaben, propylene glycol, purified water, sodium chloride, sucralose and zinc sulfate.

Questions or Comments?

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

www.efficientlabs.com

Stop use and ask a doctor if

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough, such as occurs with asthma or chronic bronchitis.

These could be signs of a serious condition.

Ask a doctor before use if the child has

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough, such as occurs with asthma or chronic bronchitis

Other Information

- store this product between 15 to 30 °C (59 to 86 °F)
- do not refrigerate
- product color & flavor may vary due to natural honey

Tamper-Evident Feature: do not use this product if printed security seal is torn, broken or missing.

Rompe Pechito

EFFICIENT®

Rompe Pechito®

DM FOR KIDS

**Bronchial Congestion
Phlegm (mucus)
Cough**

Ages 4+

WITH HONEY & ELDERBERRY

ALCOHOL FREE - DYE FREE
Dextromethorphan HBr (Cough Suppressant)
Guaifenesin (Expectorant)

NET WEIGHT: 4 FL OZ (118 mL)

Drug Facts

Active ingredients (in each 2.5 mL)

Dextromethorphan HBr, 5 mg.....Cough suppressant
Guaifenesin, 50 mg.....Expectorant

Purposes

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
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Ask a doctor before use if the child has

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough, such as occurs with asthma or chronic bronchitis.

Stop use and ask a doctor if

- 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.

Do not exceed recommended dosage.

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

Directions

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- shake well before use
- measure only with dosing cup provided
- keep dosing cup with product
- mL = milliliter

age	dose
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Questions or comments? 305-805-3486
Monday - Friday from 9 AM to 5 PM, EST or www.efficientlabs.com

Other sold formulas: Rompe Pecho® EX, Rompe Pecho® SF, Rompe Pecho® CF, Rompe Pecho® DM, Rompe Pecho® FLU, Rompe Pecho® HT, Rompe Pecho® MAX, Cough Out®, Males y Maids®.

Keep box for complete product information in Spanish.

EFFICIENT®

Rompe Pechito®

DM PARA NIÑOS

**Congestión Bronquial
Flema (mucosa)
Tos**

Edades 4+

CON MIEL Y SAUCO

SIN ALCOHOL - SIN COLORANTE
Dextrometorfano HBr (Supresor de la Tos)
Guaifenesina (Expectorante)

PESO NETO: 4 OZ FL (118 mL)

Datos Farmacológicos

Ingredientes activos (en cada 2.5 mL)

Dextrometorfano HBr, 5 mg.....Supresor de la tos
Guaifenesina, 50 mg.....Expectorante

Propósitos

Usos

- alivio temporal de la tos debido a la irritación leve de la garganta y los bronquios, asociada al resfriado común
- ayuda a desprender la flema (mucosidad) y diluye las secreciones bronquiales para drenar las vías respiratorias.

Advertencias

No lo use en niños que estén tomando un inhibidor de la monoamina oxidasa (IMAO) recetado (ciertos medicamentos para la depresión, condiciones psiquiátricas o emocionales, o la enfermedad de Parkinson), o durante 2 semanas después de suspender el medicamento IMAO. Si no sabe si el medicamento recetado de su hijo contiene un IMAO, consulte a un médico o farmacéutico antes de administrar este producto.

Consulte a su médico antes de usar si el niño padece

- tos que se presenta con exceso de flema (mucosidad)
- tos persistente o crónica, como ocurre con el asma o la bronquitis crónica.

Suspenda su uso y consulte a su médico si

- la tos persiste por más de 7 días, regresa, o se presenta acompañada por fiebre, erupción o dolor de cabeza persistente. Estos podrían ser signos de una condición grave.

No exceder la dosis recomendada.

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.

Instrucciones

- no administre más de 6 dosis en un periodo de 24 horas
- agitar bien antes de usar
- medir solo con la copa de dosificadora incluida
- mantenga la copa dosificadora con este producto
- mL = mililitros

edades	dosis
niños de 6 a menores de 12 años de edad	5 mL cada 4 horas
niños de 4 a menores de 6 años de edad	2.5 mL cada 4 horas
niños menores de 4 años de edad	no usar

Otra información

- conservar este producto entre 15 a 30 °C (59 a 86 °F)
- no refrigerar
- el color y el sabor del producto pueden variar debido a la miel natural.

Evidencia de seguridad: no utilice este producto si el sello de seguridad está rasgado, roto o falta.

Ingredientes inactivos ácido cítrico, extracto de fruta de sauco, glicerina, miel, maltodextrina, metilparabeno, sabor, sorbato de potasio como preservante, propilparabeno, propilenglicol, agua purificada, cloruro de sodio, sucralosa y sulfato de zinc.

¿Preguntas o comentarios? 305-805-3486
Lunes - Viernes de 9 AM a 5 PM, Este o www.efficientlabs.com

Other formulas: Rompe Pecho® EX, Rompe Pecho® SF, Rompe Pecho® CF, Rompe Pecho® DM, Rompe Pecho® FLU, Rompe Pecho® HT, Rompe Pecho® MAX, Cough Out®, Males y Maids®.

Conserve la caja para información completa del producto en Español.

Distributed by/Distribuido por:
Efficient Laboratories, Inc.®
Miami, FL 33166, Made in U.S.A./Hecho en EE.UU.

ROMPE PECHITO DM FOR KIDS

dextromethorphan hbr, guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58593-276
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 2.5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	50 mg in 2.5 mL

Inactive Ingredients

Ingredient Name	Strength
SUCRALOSE (UNII: 96K6UQ3ZD4)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
AMERICAN ELDERBERRY (UNII: 7610Y2190C)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
HONEY (UNII: Y9H1V576FH)	

POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ZINC SULFATE (UNII: 89DS0H96TB)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58593-276-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	08/01/2023	

Labeler - Efficient Laboratories Inc (969044932)

Registrant - Efficient Laboratories Inc (969044932)

Establishment

Name	Address	ID/FEI	Business Operations
Rnv LLC		118917568	manufacture(58593-276)

Revised: 12/2023

Efficient Laboratories Inc