

**ROMPE PECHO NIGHTTIME- acetaminophen, dextromethorphan hbr,
doxylamine succinate, phenylephrine hcl liquid
EFFICIENT LABORATORIES INC**

Active ingredients (in each 30 mL dose cup)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Doxylamine Succinate 12.5 mg

Phenylephrine HCl 10 mg

Purpose

Pain reliever/fever reducer

Cough Suppressant

Antihistamine

Nasal decongestant

Uses temporarily relieves these common cold/flu symptoms:

- minor aches and pains
- headache
- nasal congestion
- sore throat
- runny nose and sneezing
- cough
- sinus congestion and pressure
- helps clear nasal passages
- relieves cough to help you get to sleep
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 doses in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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 taking this product.
- to make a child sleep

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.**

Keep out of reach of children.

Directions

- **do not take more than directed (see Overdose warning)**
- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device. Product color & flavor may vary due to natural honey.
- mL = milliliter
- shake well before use
- keep dosing cup with product
- **Adults and Children 12 years & over:** 30 mL every 4 hours
- **Children under 12 years of age:** do not use

Inactive ingredients: blue cohosh root extract, echinacea root extract, eucalyptus oil, flavor, ginkgo bilboa leaf extract, glycerin, goldenseal root extract, honey, horehouns (flower, leaf, stern) extract, licorice root extract, menthol, methylparaben, mullein leaf extract, myrrh gum, potassium citrate, potassium sorbate, propylene glycol, prolyparaben, slippery elm bark extract, sodium chloride, sucralose, water, wild cherry bark extract, zinc sulfate.

Questions or Comments? 305-805-3456

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



EFFICIENT

Rompe Pecho®

Nighttime Severe Cold & Flu Relief

NT Nighttime

Fever
Head & Body Aches
Cough
Nasal Congestion
Runny Nose
Sneezing

with Honey

ALCOHOL FREE
Pain Reliever/Fever Reducer (**Acetaminophen**)
Cough Suppressant (Dextromethorphan HBr)
Antihistamine (Doxylamine Succinate)
Nasal Decongestant (Phenylephrine HCl)
Adults & Children 12 years & over

NET WEIGHT: 6 FL Oz (180 mL)

Drug Facts

Active Ingredients (in each 30 mL dose cup) **Purpose**
 Acetaminophen 650 mg.....Pain reliever/fever reducer
 Dextromethorphan HBr 20 mg.....Cough suppressant
 Doxylamine succinate 12.5 mg.....Antihistamine
 Phenylephrine HCl 10 mg.....Nasal decongestant

Uses temporarily relieves these common cold/flu symptoms:
 • minor aches and pains • headache • nasal congestion • sore throat
 • runny nose and sneezing • cough • sinus congestion and pressure
 • helps clear nasal passages • relieves cough to help you get to sleep • temporarily reduces fever.

Warnings
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 6 doses in 24 hours, which is the maximum daily amount for this product • with other drugs containing acetaminophen • 3 or more alcoholic drinks daily while using this product.
Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: • skin reddening • blisters • rash
 If a skin reaction occurs, stop use and seek medical help right away.
Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.
Do not use • with any other drug containing acetaminophen (prescription or nonprescription), if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
 • 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 taking this product.
 • to make a child sleep.

Ask a doctor before use if you have • liver disease
 • heart disease • high blood pressure • thyroid disease • diabetes • glaucoma • trouble urinating due to enlarged prostate gland
 • cough that occurs with too much phlegm (mucus)
 • a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
 • a sodium-restricted diet.

Ask a doctor or pharmacist before use if you are
 • taking sedatives or tranquilizers • taking the blood thinning drug warfarin.

When using this product - do not use more than directed
 • excitability may occur, especially in children • marked drowsiness may occur • avoid alcoholic drinks • alcohol, sedatives, and tranquilizers may increase drowsiness • be careful when driving a motor vehicle or operating machinery.

Stop use and ask a doctor if • nervousness, dizziness, or sleeplessness occur • pain, nasal congestion, or cough gets worse or lasts more than 7 days • new symptoms occur • fever gets worse or lasts more than 3 days • redness or swelling is present • cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

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Other cold formulas: Rompe Pecho® EX, Rompe Pecho® SF, Rompe Pecho® CF, Rompe Pecho® DM, Cough Out® and Miel® y Más®, Rompe Pecho® Max, and Rompe Pecho® FLU.

Keep box for complete instructions **Rev. 1**
 Distributed by/Distribuido por:
 Efficient Laboratories, Inc.
 Miami, FL 33166, Made in U.S.A./ Hecho en EE.UU.



EFFICIENT

Rompe Pecho®

Noche Severa Alivio de la Gripe y el Resfriado

NT Para la Noche

Fiebre
Dolor Corporal y de Cabeza
Molestias Leves
Tos
Congestión Nasal
Secreción Nasal
Estornudo

con Miel

SIN ALCOHOL
Analgésico / Reductor de fiebre (**Acetaminofén**)
Supresor de la tos (Dextrometorfan HBr)
Antihistamínico (Succinato de Doxilamina)
Descongestionante nasal (Fenilefrina HCl)
Adultos y Niños 12 años y más

PESO NETO: 6 Oz FL (180 mL)

Drug Facts (Continued)

Directions • do not take more than directed (see overdose warning) • shake well before use • measure only with dosing cup provided • keep dosing cup with product • mL = milliliter • TBSF = teaspoon • this adult product is not intended for use in children under 12 years of age.

age	dose
adults and children 12 years of age and over	30 mL every 4 hours
children under 12 years of age	do not use

Other information - each 30 mL contains: potassium 20 mg; sodium 12 mg • store between 15-30°C (59-86°F). Do not refrigerate • product color & flavor may vary due to natural honey. **TAMPER-EVIDENT FEATURE:** Do not use this product if printed safety seal is torn, broken, or missing.

Inactive ingredients blue cohosh root extract, citric acid, echinacea root extract, eucalyptus oil, flavor, ginkgo biloba leaf extract, glycerin, goldenseal root extract, honey, horhound (flower, leaf, stem) extract, licorice root extract, menthol, methylparaben, mulein leaf extract, myrrh gum, potassium citrate, 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 (9 AM - 5 PM EST) or www.efficientlabs.com

Datos Farmacológicos

Ingredientes activos (en cada copa de dosis de 30 mL) **Propósito**
 Acetaminofén 650 mg.....Analgésico antipirético
 Dextrometorfan HBr 20 mg.....Supresor de la tos
 Succinato de Doxilamina 12.5 mg.....Antihistamínico
 Clorhidrato de fenilefrina 10 mg.....Descongestionante nasal

Usos Alivia temporalmente los siguientes síntomas del resfriado común y la gripe: • malestares y dolores menores • dolor de cabeza • congestión nasal • dolor de garganta • picazón en la nariz y estornudos • reduce la tos para ayudar a dormir • congestión y presión en los senos nasales • reduce la fiebre temporalmente.

Advertencias
Advertencia acerca del hígado: este producto contiene acetaminofén. Puede producirse daño hepático grave si • toma más de 6 dosis en 24 horas, que es la cantidad diaria máxima para este producto • lo toma con otros fármacos que contengan acetaminofén • toma 3 o más copas de bebida alcohólica por día mientras usa este producto.
Alerta sobre alergia: el acetaminofén puede provocar reacciones graves en la piel. Los síntomas pueden incluir: • enrojecimiento de la piel • ampollas • sarpullido. Si se produce una reacción en la piel, suspender el uso y buscar ayuda médica de inmediato.
Advertencia acerca del dolor de garganta: si el dolor de garganta es intenso, persiste por más de 2 días, está acompañado o seguido de fiebre, dolor de cabeza, sarpullido, náuseas o vómitos, consultar a un médico de inmediato.
 No usar • con ningún otro fármaco que contenga acetaminofén (recetado o de venta libre). Si no está seguro si un fármaco contiene acetaminofén, preguntar a un médico o farmacéutico.
 • Si usted toma actualmente un inhibidor de la monoaminooxidasa (MAOI) recetado (ciertos fármacos para la depresión, afecciones psiquiátricas o emocionales, o la enfermedad de Parkinson) o durante 2 semanas después de interrumpir el fármaco MAOI.

Otros fórmulas: Rompe Pecho® EX, Rompe Pecho® SF, Rompe Pecho® CF, Rompe Pecho® DM, Cough Out® and Miel® y Más®, Rompe Pecho® Max, y Rompe Pecho® FLU.

Guarde la caja para instrucciones completas
DATOS FARMACOLOGICOS EN ESPAÑOL ADENTRO.

ROMPE PECHO NIGHTTIME			
acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58593-830
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg	in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg	in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg	in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg	in 30 mL
Inactive Ingredients			

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
MULLEIN LEAF (UNII: 9936O846LI)	
MYRRH (UNII: JC71GJ1F3L)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ULMUS RUBRA BARK (UNII: 91QY4PXU8Q)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	
PRUNUS SEROTINA BARK (UNII: 5D48E975HA)	
ZINC SULFATE (UNII: 89DS0H96TB)	
CAULOPHYLLUM THALICTROIDES ROOT (UNII: JTJ6HH6YEH)	
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GINKGO (UNII: 19FUJ2C58T)	
GLYCERIN (UNII: PDC6A3C0OX)	
GOLDENSEAL (UNII: ZW3Z11D0JV)	
HONEY (UNII: Y9H1V576FH)	
HOREHOUND (UNII: K08036XEJV)	
LICORICE (UNII: 61ZBX54883)	
MENTHOL (UNII: L7T10EIP3A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58593-830-06	1 in 1 CARTON	09/01/2019	
1		180 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/01/2019	

Labeler - EFFICIENT LABORATORIES INC (969044932)

Registrant - EFFICIENT LABORATORIES INC (969044932)