

ROMPE PECHO MAX MULTI SYMPTOMS- acetaminophen, dextromethophan hbr, phenylephrine hcl, guaifenesin liquid
EFFICIENT LABORATORIES INC

Active ingredients

Purposes

(in each 20mL)

Acetaminophen 650 mg.....Pain reliever/feverreducer

Dextromethorphan Hbr 20 mg.....Cough suppressant

Guaifenesin 400 mg.....Expectorant

Phenylephrine HCl 10 mg.....Nasal decongestant

- Pain reliever/fever reducer
- Cough suppressant
- Expectorant
- Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- minor aches and pains
- sore throat
- headache
- temporarily reduces fever
- promotes nasal and/or sinus drainage; temporarily relieves sinus congestion and pressure
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warning

Do not exceed recommended dosage.

- Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or where cough is accompanied by excessive phlegm(mucus) unless directed by a doctor.

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
- taken with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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 a pharmacist.
- Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or where cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.
- 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
- liver disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to an enlarged prostate gland
- a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema.
- a cough that is followed by excessive phlegm (mucus)

Ask a doctor or pharmacist before use if you are

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

Stop use and ask a doctor if

- a symptoms do not improve within 7 days, tends to recur, or is accompanied by a fever, rash or persistent headache. A persistent cough may be a sign of a serious condition
- nervousness, dizziness or sleeplessness occurs
- pain and nasal congestion gets worse or last more than 5 days (children) or 7 days (adults)
- fever gets worse or last more than 3 days
- redness or swelling is present or new symptoms occur.

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 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
- **adults and children 2 years of age and over:** 20 mL (4 teaspoonful) every 4 hours
- **children under 12 years of age:** consult a doctor

Inactive ingredients:

Blue cohosh, citric acid, echinacea, eucalyptus oil, ginkgo biloba, glycerin, golden seal root, honey, horehound herb, licorice root, menthol, methylparaben, mullein leaves, myrrh, potassium citrate, potassium sorbate, propylene glycol, propylparaben, slippery elm bark, sodium chloride, sucralose, water, wild cherry bark, zinc sulfate

Questions or comments?

Call **(305) 805-3456**

Monday-Friday 9 am- 5 pm EST or www.efficientlabs.com

EFFICIENT LABORATORIES

NEW PACKAGING!
(Nuevo Empaque!)

Rompe Pecho

Maximum Strength / Potencia Máxima

MAX Multi Symptoms
Múltiples Síntomas

- MUCUS / MOCOS
- COUGH / TOS
- HEADACHE / DOLOR DE CABEZA
- FEVER / FIEBRE
- NASAL DECONGESTANT
DESCONGESTIONANTE NASAL

with Natural Honey

ALCOHOL FREE / LIBRE DE ALCOHOL

PAIN RELIEVER / FEVER REDUCER (Acetaminophen)
Analgésico / Reductor de Fiebre (Acetaminofén)

COUGH SUPPRESSANT (Dextromethorphan HBr)
Supresor de la Tos (Dextrometorfano HBr)

EXPECTORANT (Guaifenesin)
Expectorante (Guaifenesina)

NASAL DECONGESTANT (Phenylephrine HCl)
Decongestionante Nasal (Fenilefrina HCl)

Adults & Children 12 years & over
Adultos y Niños 12 años y más

NET WEIGHT: 8 FL OZ (237 mL) / PESO NETO: 8 OZ FL (237 mL)

Drug Facts

Active ingredients (in each 20 mL)

Acetaminophen, 650 mg.....Pain reliever/fever reducer
Dextromethorphan, HBr 20 mg.....Cough suppressant
Guaifenesin, 400 mg.....Expectorant
Phenylephrine HCl, 10 mg.....Nasal decongestant

Purposes

Uses

- temporarily relieves these common cold and flu symptoms:
 - nasal congestion - sinus congestion and pressure
 - cough due to minor throat and bronchial irritation
 - minor aches and pains - sore throat - headache
- temporarily reduces fever - promotes nasal and/or sinus drainage
- temporarily relieves sinus congestion and pressure - helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

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 - taken with other drugs containing acetaminophen - 3 or more alcoholic drinks every day 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 have persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or where cough is accompanied by excessive phlegm (mucus) unless directed by a doctor - 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 a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease - liver disease - high blood pressure - thyroid disease - diabetes - difficulty in urination due to an enlarged prostate gland - a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema - a cough that is followed by excessive phlegm (mucus).

Ask a doctor or pharmacist before use if you are

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

When using this product do not use more than directed

Stop use and ask a doctor if

- symptoms do not improve within 7 days, tend to recur, 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 - pain and nasal congestion gets worse or last more than 5 days (children) or 7 days (adults) - fever gets worse or last more than 3 days - redness or swelling is present or new symptoms occur.

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

Keep out of reach of children.

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 right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

Other safe formulas: Rompe Pecho EX, Rompe Pecho SF, Rompe Pecho CF, Rompe Pecho DM, Cough Outfit and Mitein y Mitein, Rompe Pecho FLU and Rompe Pecho NC.

Rev. 1

Drug Facts (continued)

Directions

- do not take more than 6 doses in any 24 hours - shake well before use - measure only with dosing cup provided - keep dosing cup with product - mL = milliliter - this adult strength product is not intended for use in children under 12 years of age

age	dose
adults and children 12 years of age and over	20 mL every 4 hours
children under 12 years of age	do not use

Other information

- each (20 mL) contains: potassium 15 mg, sodium 8 mg
- product color & flavor may vary due to natural honey
- store between 15-30°C (59-86°F) - do not refrigerate
- 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, ginkgo biloba leaf extract, glycerin, goldenseal root extract, honey, horhound (flower, leaf, stem) extract, licorice root extract, menthol, methylparaben, mullein 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 to Friday from 9 am to 5 pm, EST or www.efficientlabs.com

Datos Farmacológicos

Ingredientes activos (en cada 20 mL)

Acetaminofén, 650 mg.....Analgésico/Antipirético
Dextrometorfano HBr, 20 mg.....Inhibidor de la Tos
Guaifenesina, 400 mg.....Expectorante
Fenilefrina HCl, 10 mg.....Descongestionante nasal

Propósitos

Usos

- alivia temporalmente los síntomas de resfriado común y de la gripe:
 - congestión nasal - congestión y presión en los senos paranasales
 - tos debida a irritación leve de garganta y bronquios - dolores leves y moderados - dolor de garganta - dolor de cabeza
 - reduce temporalmente la fiebre - promueve el drenaje nasal y/o de los senos paranasales - alivia temporalmente la congestión y la presión de los senos paranasales - ayuda a aliviar la flema (mucosidad) y diluye las secreciones bronquiales para eliminar la molesta mucosidad de los conductos bronquiales y hacer los más productiva.

Advertencias

Advertencia acerca del hígado: este producto contiene acetaminofén.

Puede producirse daño hepático grave si toma: - más de 6 dosis (de 20 mL cada una) en 24 horas, la cual es la cantidad diaria máxima para este producto - con otros fármacos que contengan acetaminofén - 3 o más bebidas alcohólicas diarias mientras use este producto.

Alerta sobre alergia: el acetaminofén puede provocar reacciones severas en la piel. Los síntomas pueden incluir lo siguiente: enrojecimiento de la piel, ampollas y sarpullido. Si se produce una reacción en la piel, suspender el uso y busque 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.

Datos Farmacológicos (continuación)

No utilizarlo - con cualquier otro medicamento que contenga acetaminofén (recetado o de venta libre) - si no se está seguro si el fármaco contiene acetaminofén, preguntar a un médico o farmacéutico - si tiene los síntomas o crónica, como la que ocurre con el tabaquismo, el asma, la bronquitis crónica o el enfisema, o si la tos va acompañada de un exceso de flema (moco), a menos que lo indique un médico - si está tomando inhibidores de la monoamina oxidasa (MAO) recetados (ciertos fármacos para la depresión, afecciones psiquiátricas o emocionales, o la enfermedad de Parkinson) o durante 2 semanas después de interrumpir el fármaco (MAOI), si no sabe si el fármaco recetado contiene un MAOI, preguntar a un médico o farmacéutico antes de tomar este producto.

Consulte a su médico antes de usar si padece

- enfermedad cardíaca - enfermedad hepática - hipertensión - enfermedad tiroidea - diabetes - dificultad para orinar debido al agrandamiento de la próstata - tos que se presenta con exceso de flema (mucosidad) - tos persistente o crónica tal como ocurre con el tabaquismo, asma, bronquitis crónica o enfisema.

Consulte a su médico o farmacéutico antes de usarlo si

- está tomando el fármaco anticoagulante warfarina - tomando drogas tranquilizantes o sedantes.

Cuando use este producto, no use más de lo indicado

Suspenda su uso y consulte a su médico si

- los síntomas no mejoran en 7 días, teniendo a reaparecer o van acompañados de fiebre, sarpullido o dolor de cabeza persistente. Una tos persistente puede ser un signo de una infección grave - se produce nerviosismo, mareos o insomnio - el dolor y la congestión nasal empeoran o duran más de 5 días (niños) o 7 días (adultos) - la fiebre empeora o dura más de 3 días - ocurren nuevas síntomas como hinchazón y enrojecimiento.

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

Mantener fuera del alcance de los niños.

Advertencia de sobredosis: tomar más de la dosis recomendada (sobredosis) puede provocar daño hepático. En caso de sobredosis, buscar ayuda médica o comunicarse con un centro de toxicología de inmediato. La atención médica rápida es fundamental aunque no se adviertan signos ni síntomas.

Indicaciones

- no tome más de 6 dosis en un periodo de 24 horas - agitar bien antes de usar - medir solo con la copa dosificadora incluida
- mantenga la copa dosificadora con este producto - mL = mililitro
- este producto de concentración para adultos no está diseñado para usarse en niños menores de 12 años de edad

edad	dosis
adultos y niños 12 años de edad y más	20 mL cada 4 horas
niños menores de 12 años de edad	no usar

Otra información

- cada (20 mL) contiene: 15 mg de potasio, 8 mg de sodio
- color y sabor del producto puede variar debido a que contiene miel natural
- almacenar a temperatura de 15 - 30°C (59-86°F) - no refrigerar.

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

Ingredientes inactivos

extracto de raíz de cohosh azul, ácido cítrico, extracto de raíz de equinácea, aceite de eucalipto, extracto de hoja de ginkgo biloba, glicina, raíz de sello dorado, miel, extracto de (flor, hoja, y tallo) de manzanilla, raíz de regalaz, mentol, metilparabeno, extracto de hojas de gordolobo, extracto de goma de mirra, citrato de potasio, sorbato de potasio, propilglicol, propilparabeno, extracto de corteza de olmo resabaido, cloruro de sodio, sucralosa, agua, extracto de corteza de cereza salvaje y sulfato de zinc.

¿Preguntas o comentarios? 305-805-3456
Lunes a viernes de 9 am a 5 pm, Este o www.efficientlabs.com

Otros fórmulas: Rompe Pecho EX, Rompe Pecho SF, Rompe Pecho CF, Rompe Pecho DM, Cough Outfit and Mitein y Mitein, Rompe Pecho FLU y Rompe Pecho NC.

6.7 Inch.

3.07 Inch.

NET WEIGHT: 8 FL OZ (237 mL)

ROMPE PECHO MAX MULTI SYMPTOMS

acetaminophen, dextromethophan hbr, phenylephrine hcl, guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58593-828
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PRUNUS SEROTINA BARK (UNII: 5D48E975HA)	
ZINC SULFATE (UNII: 89DS0H96TB)	
CAULOPHYLLUM THALICTROIDES ROOT (UNII: JTJ6HH6YEH)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
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)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MULLEIN LEAF (UNII: 9936O846LI)	
MYRRH (UNII: JC71GJ1F3L)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
POTASSIUM SORBATE (UNII: 1VPU26JZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ULMUS RUBRA BARK (UNII: 91QY4PXU8Q)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58593-828-08	1 in 1 CARTON	01/01/2014	
1		237 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	01/01/2014	

Labeler - EFFICIENT LABORATORIES INC (969044932)**Registrant** - EFFICIENT LABORATORIES INC (969044932)**Establishment**

Name	Address	ID/FEI	Business Operations
Dextrum Laboratories Inc.		007392322	manufacture(58593-828)

Revised: 12/2023

EFFICIENT LABORATORIES INC