

ROMPE PECHO NT NT- acetaminophen, dextromethorphan hbr, doxylamine succinate liquid
Efficient Laboratories Inc

Rompe Pecho NT

Active Ingredients:(in each 30ml doses cup) **Purpose**

Acetaminophen 650mg Pain reliever/fever reducer

Dextromethorphan HBr 20 mgCough Suppressant

Doxylamine succinate 12.5 mg Antihistamine

Purpose

Pain reliever/fever reducer

Cough Suppressant

Antihistamine

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_

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 (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.

Directions do not take more than directed (see overdose warning)

- Do not exceed more than 6 doses in any 24-hour period
- Shake well before use
- measure only with dosing cup provided
- keep dosing cup with product
- mL=miliiter TSP=teaspoonful
- 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

Uses

- temporarily relieves these common cold/flu symptoms:
- minor aches and pains • headache • sore throat • runny nose and sneezing • cough • relieves cough to help you get to sleep
- temporarily reduces fever.

Inactive ingredients: blue cohosh root extract, citric acid, echinacea root extract, eucalyptus oil, flavor, ginkgo biloba leaf extract, glycerin, goldenseal root extract, honey, horehound (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 - Friday 9AM to 5PM EST

www.efficientlabs.com

Distributed by

Efficient Laboratories, Inc., Miami, FL 33166

Made in U.S.A.

Ask a doctor or pharmacist before use if you are:

Ask a doctor or pharmacist before use if you are

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

When using this product

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.

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.

Stop use and ask a doctor if • nervousness, dizziness, or sleeplessness occur • pain 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.

NT Nighttime
Para la Noche

Rompe Pecho

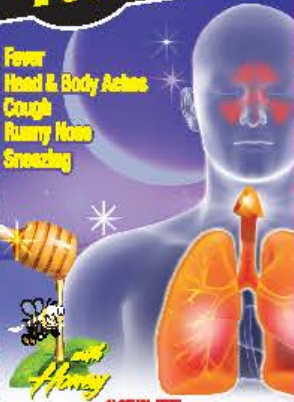
EFFICIENT

Rompe Pecho

Nighttime Severe
Cold & Flu Relief

NT Nighttime

Fever
Head & Body Aches
Cough
Runny Nose
Sneezing



ALCOHOL FREE
Pain Reliever/Fever Reducer (Acetaminophen)
Cough Suppressant (Dextromethorphan HBr)
Antihistamine (Diphenhydramine)
Active in Children 12 years & over

NET WEIGHT: 8 FL. Oz (180 mL)



Drug Facts

Active Ingredients
Per 5 mL (1 tsp) (100 mg cap)
Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Diphenhydramine 12.5 mg

Uses: Temporarily relieves these common cold symptoms:
• fever and body aches • headache • sore throat • runny nose
and sneezing • cough • relieves cough to help you get to sleep
comfortably at bedtime.

Warnings: This product contains acetaminophen. Overuse can
damage your liver if you take more than 8 doses in 24 hours,
which is the maximum daily amount for this product - with other
drugs containing acetaminophen - or more acetaminophen daily
while using this product.

Other Information: Acetaminophen may cause some skin reactions.
Some people may become drowsy or dizzy. Do not drink alcohol
while using this product. If a skin reaction occurs, stop use and seek medical help right away.

Other Warnings: If you have trouble swallowing, do not use this product.
Do not use if accompanied or followed by fever, headache, rash,
swelling or sore throat, cough, a change in voice, or difficulty
breathing.

Do not use: with any other drug containing acetaminophen,
phenylephrine or pseudoephedrine, or if you are taking another drug
containing acetaminophen, or if a doctor or pharmacist has told you
not to use this drug.

Other Information: If you are taking a prescription medicine called
MAO-A (used for depression, psychiatric or anesthesia
medication, or Parkinson's disease), or for 2 weeks after stopping the
MAO-A, do not use this product unless your doctor tells you to.

Other Information: Tell your doctor or pharmacist before use if you are
• taking any other drug containing acetaminophen
• taking any other drug containing pseudoephedrine
• taking any other drug containing phenylephrine

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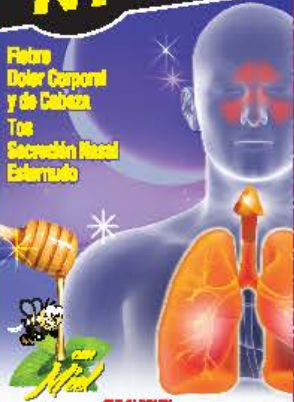
EFFICIENT

Rompe Pecho

Night Severe
Aflor de la Gripe y el Resaca

NT Para la Noche

Fatiga
Dolor Corporal
y de Cabeza
Tos
Secreción Nasal
Estornudo



ALCOHOL FREE
Analgésico / Reductor de Fiebre (Acetaminofeno)
Supresor de la Tos (Dextrometorfano HBr)
Antihistamínico (Difenhidramina)

Activo en Niños 12 años y más

PESO NETO: 8 Oz FL. (180 mL)

Drug Facts (Spanish)

Indicaciones: • No use este medicamento si usted tiene fiebre o dolor de cabeza que no se va con otros medicamentos. No use este medicamento si usted tiene problemas de salud que no se han resuelto con otros medicamentos. No use este medicamento si usted tiene problemas de salud que no se han resuelto con otros medicamentos.

Advertencias: Este medicamento contiene acetaminofeno. El uso excesivo puede dañar su hígado. No tome más de 8 dosis en 24 horas, que es la cantidad máxima permitida para este medicamento. No tome otros medicamentos que contengan acetaminofeno al mismo tiempo que este medicamento.

Advertencias: Este medicamento puede causar somnolencia o mareos. No tome alcohol mientras usa este medicamento. Si ocurre una reacción alérgica, deje de usar el medicamento y busque atención médica de inmediato.

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NET 107822

ROMPE PECHO NT NT

acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58593-003
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: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM CITRATE ANHYDROUS (UNII: 86R1NVR0HW)	
CAULOPHYLLUM THALICTROIDES ROOT (UNII: JTJ6HH6YEH)	
GLYCERIN (UNII: PDC6A3C0OX)	
ECHINACEA ANGUSTIFOLIA ROOT (UNII: D982V7VT3P)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GINKGO BILOBA LEAF OIL (UNII: Y5967KO1JH)	
GOLDENSEAL (UNII: ZW3Z11D0JV)	
HONEY (UNII: Y9H1V576FH)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
HOREHOUND (UNII: K08036XEJV)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
LICORICE (UNII: 61ZBX54883)	
MULLEIN LEAF (UNII: 9936O846LI)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
ULMUS RUBRA BARK (UNII: 91QY4PXU8Q)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PRUNUS SEROTINA BARK (UNII: 5D48E975HA)	
ZINC SULFATE (UNII: 89DS0H96TB)	
MYRRH (UNII: JC71GJ1F3L)	

SUCRALOSE (UNII: 96K6UQ3ZD4)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58593-003-06	180 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/01/2023	

Labeler - Efficient Laboratories Inc (969044932)

Registrant - Efficient Laboratories Inc (969044932)

Revised: 10/2024

Efficient Laboratories Inc