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

Paint reliever/fever reducer

Cough Suppressant

Antihistamine

Nasal decongestant

Uses temporarily relieves these common cold/flu symtoms:

- 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. Sever 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 sever 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 sever, 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 acetaminphen, 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 you prescription drug contains a MAOI, ask a doctor or pharmalacist 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 draowsiness may occur
- acoid 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.

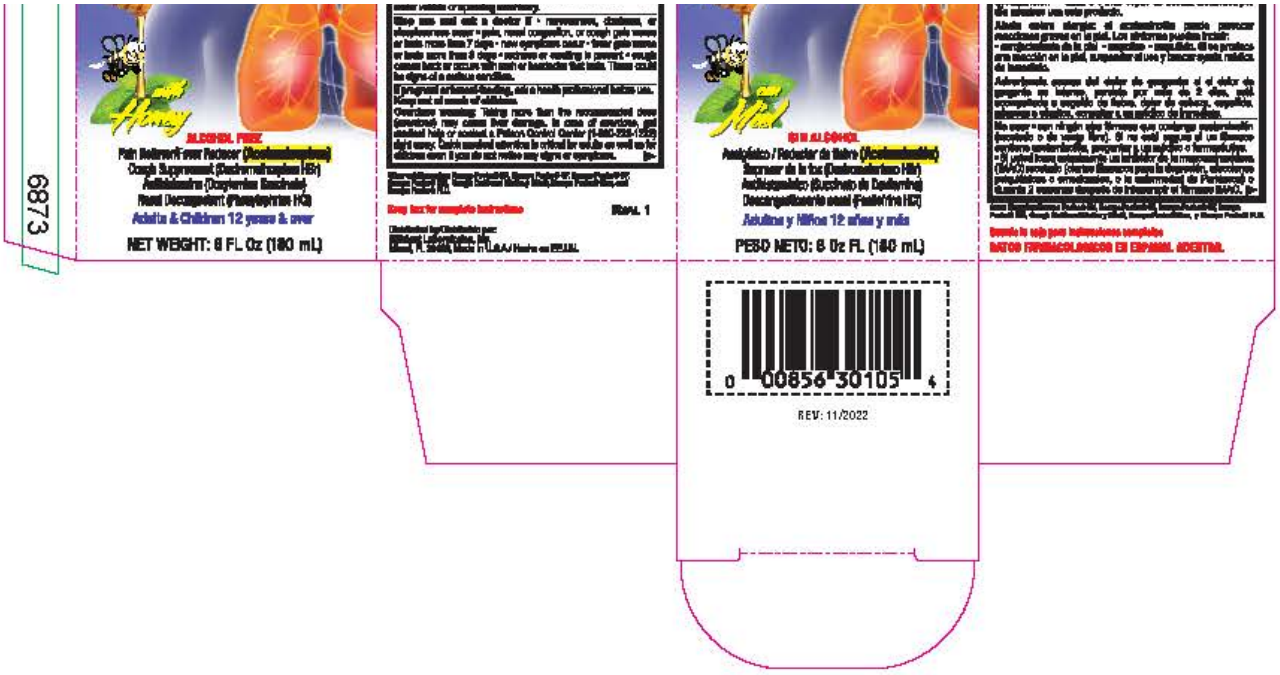
Directions

- **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, prolylparaben, 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



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: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -	PHENYLEPHRINE	10 mg

UNII:1WS297W6MV)	HYDROCHLORIDE	in 30 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
MYRRH (UNII: JC71GJ1F3L)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ULMUS RUBRA BARK (UNII: 91QY4PXU8Q)	
MULLEIN LEAF (UNII: 9936O846LI)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	
PRUNUS SEROTINA BARK (UNII: 5D48E975HA)	
ZINC SULFATE (UNII: 89DS0H96TB)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
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	11/30/2026
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	11/30/2026

Labeler - EFFICIENT LABORATORIES INC (969044932)

Registrant - EFFICIENT LABORATORIES INC (969044932)