

**ROMPE TOS X CHILDREN- acetaminophen, dextromethorphan hbr,
guaifenesin, phenylephrine hcl syrup
OPMX LLC**

Rompe Tos X Children

Drug Facts

Active ingredients

Purpose

Active ingredients (in each 10 mL = 2 teaspoonful)	Purpose
Acetaminophen 250 mg	Pain reliever/fever reducer
Dextromethorphan HBr 13.33 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

temporarily relieves these common cold/flu symptoms:

- sinus congestion & pressure
- minor aches & pains
- nasal congestion
- cough due to minor throat & bronchial irritation
- sore throat
- headache
- temporarily reduces fever
- temporarily promotes nasal and/or sinus drainage
- 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 hrs, which is the maximum daily amount for this product
- 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 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.
- for children under 12 years of age
- 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

- liver disease
- heart disease
- diabetes
- thyroid disease
- high blood pressure
- trouble urinating due to enlarged prostate gland
- persistent or chronic cough such as smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sodium restricted diet

When using this product

- do not exceed recommended dose (see overdose warning)

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
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning

Taking more than 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 for adults & for children even if you do not notice any signs or symptoms.

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 dosing cup with other products
- dose as follows or as directed by a doctor
- mL = milliliter
- tsp = teaspoonful

Age	Dose
Children 6 to under 12 years of age	10 mL or 2 tsp provided every 4 hours
Children under 6 years of age	do not use

Other information

- **each 10 mL contains**
- sodium 10 mg
- Store between 20-25°C (68-77°F)
- do not refrigerate
- keep carton for complete Drug facts

Inactive ingredients

Aloe vera, citric acid, disodium EDTA, FD&C red no. 40, hydroxyethyl cellulose, natural & artificial strawberry flavor, propylene glycol, purified water, sodium benzoate, sorbitol 70%, sucralose

Questions?

Call 616-600-5632 MON to FRI, 9 a.m. to 6 p.m. PTZ

PRINCIPAL DISPLAY PANEL - 177 mL Bottle Label

NDC 69729-784-06

Rompe Tos X

6 fl oz (177 mL)

Children SYRUP

ROMPE TOSX

NDC 69729-784-06

ROMPE TOSX



JARABÉ Infantil

Fiebre y Dolor de Cabeza
(Acetaminophen)

Control de la Tos
(Dextromethorphan HBr)

Adelgaza y Expulsa las Flemas
(Guaifenesin)

Congestión Nasal
(Phenylephrine HCl)

Gripe, Resfriado & Garganta Irritada

Caja con frasco de 6 fl oz (177 mL) y vasito dosificador

Drug Facts

Active Ingredients Purpose
(in each 10 mL = 2 teaspoonful)

Acetaminophen 250 mg Pain reliever/fever reducer
Dextromethorphan HBr 13.33 mg Cough suppressant
Guaifenesin USP 200 mg Expectorant
Phenylephrine HCl 5 mg Nasal decongestant

Uses

Temporarily relieves these common cold and flu symptoms:
 ■ sinus congestion and pressure
 ■ minor aches and pains ■ nasal congestion
 ■ cough due to minor throat and bronchial irritation
 ■ sore throat ■ headache
 ■ temporarily reduces fever
 ■ temporarily promotes nasal and/or sinus drainage
 ■ helps loosen phlegm (mucus) and thin bronchial secretions to visit 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.
 ■ 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 redness/itching ■ hives ■ 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.
 ■ for children under 12 years of age
 ■ 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:

■ liver disease ■ heart disease ■ diabetes
 ■ thyroid disease ■ high blood pressure
 ■ trouble urinating (due to an enlarged prostate gland)
 ■ persistent or chronic cough such as occurs with smoking, asthma chronic bronchitis, or emphysema
 ■ cough that occurs with too much phlegm (mucus)
Ask a doctor or pharmacist before use if you are:
 ■ taking the blood thinning drug warfarin
 ■ taking sodium restricted diet

When using this product:

■ do not exceed recommended dose (see overdose warning)

Stop use and ask a doctor if:

■ new/nausea, dizziness, or sleepiness occur
 ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days

Drug Facts (continued)

■ fever gets worse or lasts more than 3 days
 ■ redness or swelling is present
 ■ new symptoms occur
 ■ cough comes back or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

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.

Directions

■ **do not take more than directed** (see **Overdose warning**)
 ■ do not take more than 6 doses in any 24 hour period
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Other information

■ each 10 mL contains:
 ■ sodium 10 mg
 ■ store between 20-25°C (66-77°F)
 ■ do not refrigerate
 ■ keep carton for complete Drug Facts

Inactive ingredients

Also see: citric acid, disodium EDTA, FD&C red no. 40, hydroxyethyl cellulose, natural & artificial strawberry flavor, propylene glycol USP, purified water, sodium benzoate, sorbitol 70% USP, sucrose.

Questions?

Call 619-600-5632 MON to FRI, 9 a.m. to 6 p.m. PTZ

VERSIÓN EN ESPAÑOL EN EL INTERIOR DE LA CAJA

PARENTS:
www.bupha.com/parents
 PUD-42828 18003323



Exclusively distributed by:
CPMx
 Chula Vista, CA 91910
 Phone: 619-600-5632



ROMPE TOSX

NDC 69729-784-06



Children SYRUP

Headache & Fever
(Acetaminophen)

Controls Cough
(Dextromethorphan HBr)

Thins & Loosens Mucus
(Guaifenesin)

Nasal Congestion
(Phenylephrine HCl)

Cold, Flu & Sore Throat

Box with bottle with 6 fl oz (177 mL) and measuring cup

Rev. 09/2023
 Item # IN0148



Lot No.

Exp.

NO VANISH AREA

ROMPE TOS X CHILDREN

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl syrup

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69729-784

Route of Administration

ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	13.33 mg in 10 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ALOE (UNII: V5VD430YW9)	
SORBITOL SOLUTION 70% (UNII: 8KW3E207O2)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-784-06	1 in 1 CARTON	09/18/2023	
1		177 mL in 1 BOTTLE, PLASTIC; 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	09/18/2023	

Labeler - OPMX LLC (029918743)

Establishment

Name	Address	ID/FEI	Business Operations
GADAL Laboratories, Inc		841305639	manufacture(69729-784)

Revised: 3/2025

OPMX LLC