

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

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**Rompe Tos X Adult**

***Drug Facts***

***Active ingredients***

**Purpose**

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***Active ingredients (in each 20 mL)***

Acetaminophen 500 mg  
Dextromethorphan HBr 26.66 mg  
Guaifenesin 400 mg  
Phenylephrine HCl 10 mg

***Purpose***

Pain reliever/fever reducer  
Cough suppressant  
Expectorant  
Nasal decongestant

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***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

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Age	Dose
adults and children 12 years of age and older	20 mL in dosing cup provided every 4 hours
Children under 12 years of age	do not use

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### **Other information**

- **each 20 mL contains**
- sodium 20 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 solution, 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 69729-785-06

Rompe Tos X

6 fl oz (177 mL)



ROMPE TOS X ADULTS		
acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl syrup		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)
Route of Administration	ORAL	NDC:69729-785

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg in 20 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	26.66 mg in 20 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL

**Inactive Ingredients**

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

**Product Characteristics**

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	STRAWBERRY	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-785-06	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(69729-785)

Revised: 3/2025

OPMX LLC