

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

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69729-785
<b>Route of Administration</b>	ORAL		

**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>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<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)	

**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 final	part341	09/18/2023	

**Labeler** - OPMX LLC (029918743)

## Establishment

Name	Address	ID/FEI	Business Operations
GADAL Laboratories, Inc		841305639	manufacture(69729-785)

Revised: 9/2023

OPMX LLC