

**TESALON JARABE ADULTO- acetaminophen, dextromethorphan hbr,  
guaifenesin usp, phenylephrine hcl syrup  
OPMX LLC**

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**Tesalon Multi Symptom Relief**

***Drug Facts***

***Active ingredients***

***Purposes***

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

Acetaminophen 500 mg  
Dextromethorphan HBr 26.66 mg  
Guaifenesin USP 400 mg  
Phenylephrine Cl 10 mg

***Purposes***

Pain reliever/fever reducer  
Cough suppressant  
Expectorant  
Nasal decongestant

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***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 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 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 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 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.

### **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 fever, rash, or headache that lasts.  
These could be signs of a serious condition.

### **If pregnant or breast-feeding,**

ask health professional before use

## **Keep out of reach of children**

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

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**

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

## **Other information**

each 10 mL contains:

sodium 10mg

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 or comments?**

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

NDC 69729-787-06

Tesalon®

Alivia Múltiples-Síntomas

Gripe, Resfriado & Garganta Irritada

Máxima Potencia

Alivia Fiebre y Dolor de Cabeza  
(Acetaminophen)

Control de la Tos  
(Dextromethorphan HBr)

Adelgaza y Expulsa las Flemas  
(Guaifenesin)

Alivia la Congestión Nasal  
(Phenylephrine HCl)

Alivio hasta por 8 horas

Caja con frasco de 6FL OZ (177mL)

y vasito dosificador

NDC 69729-787-06

Tesalon®

Multi-Sympton Relief

Cold, Flu & Sore Throat

Maximum Strength

Relieves Headache & Fever  
(Acetaminophen)

Controls Cough  
(Dextromethorphan HBr)

Thins & Loosens Mucus  
(Guaifenesin)

Relieves Nasal Congestion  
(Phenylephrine HCl)

Relief up to 8 hours

Box with bottle of 6 FL OZ (177mL)

and measuring cup

Tampering evident: DO NOT USE IF PRINTED SAFETY SEAL AROUND OR UNDER CAP IS  
BROKEN OR MISSING.

VERSIÓN EN ESPAÑOL EN EL INTERIOR DE LA CAJA

NDC 69729-787-06



*Alivia Múltiples-Síntomas*

Gripe, Resfriado & Garganta Irritada

Máxima Potencia

- Alivia Fiebre y Dolor de Cabeza (Acetaminophen)
- Control de la Tos (Dextromethorphan HBr)
- Adelgaza y Expulsa las Flemas (Guaifenesin)
- Alivia la Congestión Nasal (Phenylephrine HCl)

ALIVIO HASTA POR  8 horas

Caja con frasco de 6 FL OZ (177 mL) y vasito dosificador

NDC 69729-787-06

**Drug Facts**

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

Acetaminophen 500 mg Pain reliever/fever reducer  
Dextromethorphan HBr 26.66 mg Cough suppressant  
Guaifenesin USP 400 mg Expectorant  
Phenylephrine HCl 10 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 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 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 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 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**

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days

Tesalon

*Multi-Symptom Relief*

Cold, Flu & Sore Throat

Maximum Strength

- Relieves Headache & Fever (Acetaminophen)
- Controls Cough (Dextromethorphan HBr)
- Thins & Loosens Mucus (Guaifenesin)
- Relieves Nasal Congestion (Phenylephrine HCl)

RELIEF UP TO  8 hours

Box with bottle of 6 FL OZ (177 mL) and measuring cup

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND OR UNDER CAP IS BROKEN OR MISSING.

**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
- 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
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

**Other information**

- each 20 mL contains:
  - sodium 20 mg ■ store between 20-25°C (68-77°F)
  - do not refrigerate

**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 or comments?**  
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:

Learn more from experts here:  
[www.DrugFacts.com](http://www.DrugFacts.com)

FLD-A282B L8003323



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Made for



San Diego, CA



Made in USA with foreign & domestic ingredients

## TESALON JARABE ADULTO

acetaminophen, dextromethorphan hbr, guaifenesin usp, phenylephrine hcl syrup

Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69729-787
<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>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	26.66 mg in 20 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL

Inactive Ingredients	
Ingredient Name	Strength
<b>ALOE</b> (UNII: V5VD430YW9)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>HYDROXYETHYL CELLULOSE, UNSPECIFIED</b> (UNII: T4V6TWG28D)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	

<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C RED NO. 4</b> (UNII: X3W0AM1JLX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

### 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:69729-787-06	1 in 1 CARTON	09/27/2024	
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	09/27/2024	

**Labeler** - OPMX LLC (029918743)

### Establishment

Name	Address	ID/FEI	Business Operations
GADAL Laboratories, Inc		841305639	manufacture(69729-787)

Revised: 10/2024

OPMX LLC