# TESALON CHILDREN- acetaminophen, dextromethorphan hbr, guafeisin usp, phenylephrine hcl syrup OPMX LLC ----Tesalon Children Multi-Symptom Drug Facts Active Ingredients Active Ingredients \_\_\_\_\_\_Purposes (in each 10mL= 2 teaspoonfull) Acetaminophen 250mg ........Pain reliever/fever reducer Dextromethorphan HBr 13.33mg........Cough suppressant Guaifesin USP 200mg........Expectorant Phenylephrine HCl 5mg......Nasal descongestant

### **Purpose**

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

### Uses

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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 Parkison'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
- 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

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### 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

Children 6 to under 12 years of age 10mL or 2 tsp in dosing cup provided every 4 hours Children under 6 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 USP, purified water, sodium benzoate, sorbitol 70% USP, sucralose.

### Questions or comments?

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

# **Principal Display Panel**

NDC 69729-786-06

Tesalon®

Infantil

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 HCI)

Alivio hasta por 8 horas

Caja con frasco de 6FL OZ (177mL)

y vasito dosificador

NDC 69729-786-06

Tesalon®

Children

Cold, Flu & Sore Throat

Maximum Strenght

• Relieves Headache & Fever

(Acetaminophen)

• Controls Cough

(Dextromethorphan HBr)

• Thins & Loosens Mucus

(Guaifenesin)

• Relieves Nasal Congestion

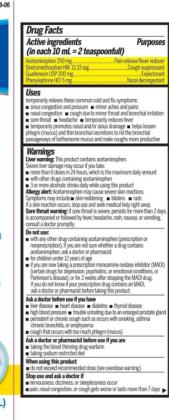
(Phenylephrine HCI)

Relief up to 8 hours

Box with bottle of 6 FL OZ (177mL)

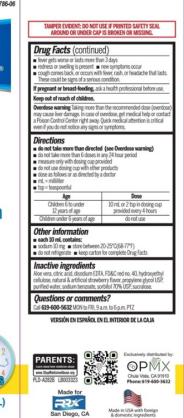
and measuring cup







and measuring cup



### **TESALON CHILDREN**

acetaminophen, dextromethorphan hbr, quafeisin usp, phenylephrine hcl syrup

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-786
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	13.33 mg in 10 mL	
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	ACETAMINOPHEN	250 mg in 10 mL	

Inactive Ingredients	
Ingredient Name	Strength

SORBITOL SOLUTION 70% (UNII: 8KW3E20702)

SODIUM BENZOATE (UNII: OJ245FE5EU)

HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)

FD&C RED NO. 40 (UNII: WZB9127XOA)

WATER (UNII: 059QF0KO0R)

EDETATE DISODIUM (UNII: 7FLD91C86K)

ALOE (UNII: V5VD430YW9)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

SUCRALOSE (UNII: 96K6UQ3ZD4)

Product Characteristics			
Color	red	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729- 786-06	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	<b>Business Operations</b>
GADAL Laboratories, Inc		841305639	manufacture(69729-786)

Revised: 9/2024 OPMX LLC