

**TESALON CHILDREN- acetaminophen, dextromethorphan hbr, guaifeisin usp,
phenylephrine hcl syrup
OPMX LLC**

Tesalon Children Multi-Symptom

Drug Facts

Active Ingredients

Active Ingredients _____ Purposes

(in each 10mL= 2 teaspoonfull)

Acetaminophen 250mgPain reliever/fever reducer
Dextromethorphan HBr 13.33mg.....Cough suppressant
Guaifesisin USP 200mg.....Expectorant
Phenylephrine HCl 5mg.....Nasal descongellant

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

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
- 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**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 HCl)

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 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

NDC 69729-786-06



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

Glue - No Coating

NDC 69729-786-06



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

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- 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 in dosing cup 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

Alco 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?
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Made for

San Diego, CA



Made in USA with foreign & domestic ingredients

TESALON CHILDREN

acetaminophen, dextromethorphan hbr, guaifenesin 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	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	13.33 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength

SORBITOL SOLUTION 70% (UNII: 8KW3E207O2)	
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			

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	Business Operations
GADAL Laboratories, Inc		841305639	manufacture(69729-786)