TENALIF CHILDREN- 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.

Tenalif Children

Drug Facts

Active ingredients

Purpose

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

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 sush 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 damaage. 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

Age	Dose
Children 6 to under 12 years of age	10 mL or 2 tsp 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

Aloe vera, citric acid, disodium EDTA, FD&C red no. 40, hydroxyethyl cellulose, natural & artificial strawberry flavor, propylene glycol, purified water, sodium benzoate, sorbitol 70%, 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 69729-070-06

Tenalif Children

6 fl oz (177 mL)

TENALIF CHILDREN

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl syrup

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69729-070
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	13.33 mg in 10 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ALOE (UNII: V5VD430YW9)	
SORBITOL SOLUTION 70% (UNII: 8KW3E207O2)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
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:69729-070-06	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(69729-070)

Revised: 9/2023 OPMX LLC