

TRIAMINIC NIGHT TIME COLD AND COUGH- diphenhydramine hcl, phenylephrine hcl syrup

GlaxoSmithKline Consumer Healthcare Holdings (US) 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.

Drug Facts

Active ingredients (in each 5 mL)

Diphenhydramine HCl 6.25 mg

Phenylephrine HCl 2.5 mg

Purposes

Antihistamine/cough suppressant

Nasal decongestant

Uses

- temporarily relieves
 - sneezing
 - itchy nose or throat
 - runny nose
 - itchy, watery eyes due to hay fever
 - nasal and sinus congestion
 - cough due to minor throat and bronchial irritation as may occur with a cold

Warnings

Do not use

- in a child under 4 years of age
- in a child who is 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 the child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.
- with any other product containing diphenhydramine, even one used on skin
- for the purpose of making your child sleepy

Ask a doctor before use if the child has

- heart disease
- high blood pressure
- thyroid disease
- diabetes

- glaucoma
- cough that occurs with too much phlegm (mucus)
- chronic cough that lasts or as occurs with asthma
- a breathing problem such as chronic bronchitis

Ask a doctor or pharmacist before use if the child is
taking sedatives or tranquilizers

When using this product

- **do not exceed recommended dosage**
- may cause marked drowsiness
- sedatives and tranquilizers may increase drowsiness
- excitability may occur, especially in children

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occurs
- symptoms do not improve within 7 days or occur with a fever
- cough persists for more than 7 days, comes back or occurs with a fever, rash or persistent headache. These could be signs of a serious condition.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- may be given every 4 hours. Do not give more than 6 doses in 24 hours unless directed by a doctor
- use enclosed dosing cup only. Keep for use with this product only. Do not use any other dosing device.

Age	Dose
children under 4 years of age	do not use
children 4 to under 6 years of age	do not use unless directed by a doctor
children 6 to under 12 years of age	10 mL

Other information

- **each 5 mL contains:** sodium 3 mg
- store at 20-25°C (68°-77°F)

Inactive ingredients

acesulfame potassium, anhydrous citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavor, maltitol solution, propylene glycol, purified water, sodium benzoate, sodium citrate

Questions or comments?

call **1-800-452-0051**

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Principal Display Panel

NDC 0067-8106-04

Ages 6 to 11 years

Children's Triaminic[®] Syrup

Night Time Cold & Cough

Diphenhydramine HCl (Antihistamine/Cough Suppressant)

Phenylephrine HCl (Nasal Decongestant)

- Cough Relief
- Runny, Stuffy Nose
- Itchy Throat

Grape Flavor

4 Fl OZ (118 mL)

Child-Resistant Safety Cap.

Do not use if printed neckband is broken or missing.

What You Need to Help Make Your Child Feel Better

Night Time Cold & Cough

- Cough Relief
- Runny, Stuffy Nose
- Itchy Throat

The Triaminic brand provides a broad range of products, created with the needs of children in mind.

Trusted by Parents for over 50 years.

For more information plus helpful tips visit www.triaminic.com or call The Triaminic Clinic[®], 1-800-KIDS-987

12682

Ages 6 to 11 Years

NDC 0087-8106-04

Children's

Triaminic[®]
Syrup

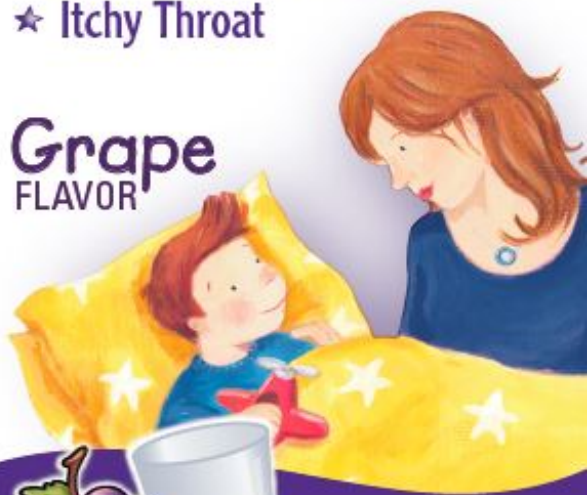



**Night Time
Cold
& Cough**

Diphenhydramine HCl
(Antihistamine/Cough Suppressant)
Phenylephrine HCl (Nasal Decongestant)

- ★ Cough Relief
- ★ Runny, Stuffy Nose
- ★ Itchy Throat

Grape
FLAVOR



4 FL OZ (118 mL)

TRIAMINIC NIGHT TIME COLD AND COUGH

diphenhydramine hcl, phenylephrine hcl syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0067-8106
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	6.25 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTITOL (UNII: D65DG142WK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-8106-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/15/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/15/2012	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 12/2020

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC