TOPCARE CHILDRENS NIGHT TIME COLD AND COUGH- diphenhydramine hydrochloride, phenylephrine hydrochloride solution
Topco Associates 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.

Topco Associates LLC. Children's Night Time Cold & Cough 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 your 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
- to make a 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 get better within 7 days or occur with fever
- cough persists for more than 7 days, comes back, or occurs with fever, rash or persistent headache. A persistent cough may be a sign 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 (1-800-222-1222).

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 #1, FD&C red #40, flavor, maltitol solution, propylene glycol, purified water, sodium benzoate, sodium citrate

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

COMPARE TO CHILDREN'S TRIAMINIC® NIGHT TIME COLD & COUGH ACTIVE INGREDIENTS

TRIACTING SYRUP

children's Night Time Cold & Cough

ANTIHISTAMINE – COUGH SUPPRESSANT

DIPHENHYDRAMINE HCl

NASAL DECONGESTANT – PHENYLEPHRINE HCl

Cough Relief

Runny & Stuffy Nose

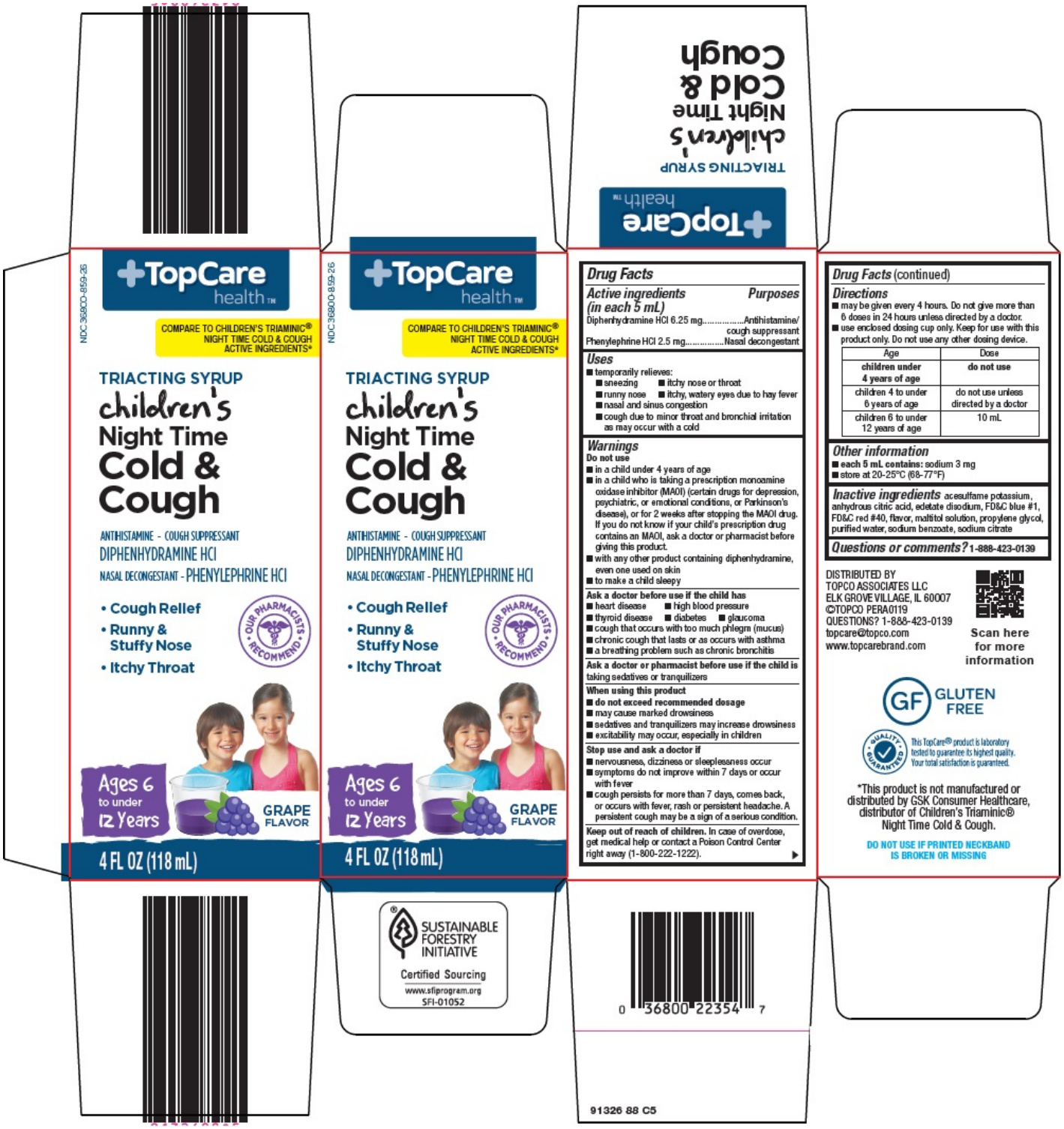
Itchy Throat

OUR PHARMACISTS RECOMMEND

Ages 6 to under 12 Years

GRAPE FLAVOR

4 FL OZ (118 mL)



TOPCARE CHILDRENS NIGHT TIME COLD AND COUGH

diphenhydramine hydrochloride, phenylephrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-859
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)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Product Characteristics			
Color	PURPLE	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:36800-859-26	1 in 1 CARTON	04/16/2019	
1		118 mL in 1 BOTTLE; 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	04/16/2019	

Labeler - Topco Associates LLC (006935977)

Revised: 4/2019 Topco Associates LLC