

**TRIAMINIC DAY TIME COLD AND COUGH AND NIGHT TIME COLD AND COUGH-  
dextromethorphan hbr, phenylephrine hcl and diphenhydramine hcl, phenylephrine hcl  
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.*

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**Drug Facts**

**Day Time Cold & Cough – Ages: 4 years & up**

***Active ingredients (in each 5 mL)***

Dextromethorphan HBr 5 mg

Phenylephrine HCl 2.5 mg

***Purposes***

Cough suppressant

Nasal decongestant

***Uses***

- temporarily relieves
  - 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.

**Ask a doctor before use if your child has**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- cough that occurs with too much phlegm (mucus)
- chronic cough that lasts, or as occurs with asthma

**When using this product**

- **do not exceed recommended dosage**

**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
<b>children under 4 years of age</b>	<b>do not use</b>
children 4 to under 6 years of age	5 mL
children 6 to under 12 years of age	10 mL

**Other information**

- store at 20°-25°C (68°-77°F)

**Inactive ingredients**

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

**Questions or comments?**

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

**Night Time Cold & Cough – Ages: 6 years & up**

**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
<b>children under 4 years of age</b>	<b>do not use</b>
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**

**Principal Display Panel**

Children’s Triaminic® Syrup  
 DAY/NIGHT VALUE PACK

**Day Time Cold & Cough**

**Ages 4-11 Years**

Dextromethorphan HBr (Cough Suppressant)

Phenylephrine HCl (Nasal Decongestant)

- Stuffy Nose
- Cough

Cherry Flavor

4 FL OZ (118 mL)

## **Night Time Cold & Cough**

**Ages 6 to 11 years**

Diphenhydramine HCl (Antihistamine/Cough Suppressant)

Phenylephrine HCl (Nasal decongestant)

- Cough Relief
- Runny, Stuffy Nose
- Itchy Throat

Grape Flavor

4 FL OZ (118 mL)

**8 FL OZ (236 mL) TOTAL**

**Do not give both products at the same time or give more than 6 doses in total in any 24 hour period.**

**Child-Resistant Safety Cap.**

**Do not use if printed neckband is broken or missing.**

**What You Need to help Make Your Child Feel Better**

**PARENTS: Learn about teen medicine abuse**

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

**DO NOT GIVE THE FIRST DOSE OF NIGHT TIME COLD & COUGH SOONER THAN 4 HOURS AFTER THE LAST DOSE OF DAY TIME COLD & COUGH UNLESS DIRECTED BY A DOCTOR.**

**DO NOT GIVE BOTH PRODUCTS AT THE SAME TIME OR GIVE MORE THAN 6 DOSES IN TOTAL IN ANY 24 HOUR PERIOD.**

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**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](http://www.triaminic.com) or call The Triaminic Clinic©, 1-800-KIDS-987**

Ages 4 to 11 Years

Ages 6 to 11 Years

Children's

# Triaminic<sup>®</sup> Syrup



## Day Time Cold & Cough

**Dextromethorphan HBr  
(Cough Suppressant)**

**Phenylephrine HCl (Nasal Decongestant)**

- ★ Stuffy Nose
- ★ Cough



**Cherry  
FLAVOR**



4 FL OZ (118 mL)



## 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)

8 FL OZ (236 mL) TOTAL

**TRIAMINIC DAY TIME COLD AND COUGH AND NIGHT TIME COLD AND COUGH**

dextromethorphan hbr, phenylephrine hcl and diphenhydramine hcl, phenylephrine hcl kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0067-8112
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**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-8112-08	1 in 1 CARTON; Type 0: Not a Combination Product	01/01/2016	

**Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	118 mL
Part 2	1 BOTTLE	118 mL

**Part 1 of 2****TRIAMINIC DAY TIME COLD AND COUGH**

dextromethorphan hbr, phenylephrine hcl syrup

**Product Information**

<b>Item Code (Source)</b>	NDC:0067-8105
<b>Route of Administration</b>	ORAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 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 RED NO. 40 (UNII: WZB9127XOA)	
MALTITOL (UNII: D65DG142WK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	

## Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-8105-04	118 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	10/15/2012	

## Part 2 of 2

### TRIAMINIC NIGHT TIME COLD AND COUGH

diphenhydramine hcl, phenylephrine hcl syrup

## Product Information

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: 059QF0KO0R)

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		

### Marketing Information

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

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2016	

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

Revised: 1/2016

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC