

TRIACTING DAYTIME COLD COUGH CHILDRENS- dextromethorphan hbr, phenylephrine hcl syrup

Safeway, Inc.

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)

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 the 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 (1-800-222-1222) right away.

Directions

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device
- keep dosing cup with product
- mL = milliliter
- shake well before using

age	dose
children 6 to under 12 years of age	10 mL every 4 hours
children 4 to 6 years of age	5 mL every 4 hours
children under 4 years of age	do not use

Other information

- **each 5 mL contains:** sodium 2 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

acesulfame potassium, alcohol, benzoic acid, citric acid, disodium EDTA, FD&C red #40, maltitol, flavor, propylene glycol, purified water, sodium citrate

Questions or comments?

Call **1-888-723-3929** Monday-Friday 7AM-6PM PST

Principal Display Panel

Compare to Children's Triaminic® Day Time Cold & Cough active ingredients*

Children's Daytime**Cold & Cough Relief**

FOR AGES 4-11 YEARS

Dextromethorphan HBr 5 mg-Cough suppressant

Phenylephrine HCl 2.5 mg-Nasal decongestant

- Relief of: Cough, stuffy nose
- Alcohol 0.14%
- Dosing cup included

CHERRY FLAVOR

FL OZ (mL)

*This product is not manufactured or distributed by GSK Consumer Health, distributors of Children's Triaminic® DayTime Cold & Cough.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING

DISTRIBUTED BY
 BETTER LIVING BRANDS LLC
 P.O. BOX 99, PLEASANTON, CA
 94566-0009
 www.betterlivingbrandsLLC.com

Package Label

<p>Drug Facts (continued)</p> <p>Other information</p> <ul style="list-style-type: none"> each 5 mL contains: sodium 2 mg store between 20-25°C (68-77°F). Do not refrigerate. <p>Inactive ingredients acetylsalicylic acid, alcohol, benzoic acid, citric acid, disodium EDTA, FD&C red #40, flavor, maltitol, propylene glycol, purified water, sodium citrate</p> <p>Questions or comments? Call 1-888-723-3929 Monday-Friday 7AM-6PM PST</p>	<p>Compare to Children's Triaminic® Day Time Cold & Cough active ingredients* NDC 21130-378-04</p> 	<p>Compare to Children's Triaminic® Day Time Cold & Cough active ingredients* NDC 21130-378-04</p> 	<p>Drug Facts</p> <p>Active ingredients (in each 5 mL)</p> <p>Dextromethorphan HBr 5 mg.....Cough suppressant Phenylephrine HCl 2.5 mg.....Nasal decongestant</p> <p>Purposes</p> <p>Uses</p> <ul style="list-style-type: none"> temporarily relieves nasal and sinus congestion cough due to minor throat and bronchial irritation as may occur with a cold <p>Warnings</p> <p>Do not use</p> <ul style="list-style-type: none"> 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. <p>Ask a doctor before use if the child has</p> <ul style="list-style-type: none"> 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 <p>When using this product, do not exceed recommended dosage.</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> nervousness, dizziness or sleeplessness occurs symptoms do not improve within 7 days or occur with fever cough persists more than 7 days, comes back or occurs with a fever, rash, or persistent headache. These could be signs of a serious condition. <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p> <p>Directions</p> <ul style="list-style-type: none"> do not give more than 6 doses in any 24-hour period measure only with dosing cup provided. Do not use any other dosing device. keep dosing cup with product mL = milliliter shake well before using <table border="1"> <thead> <tr> <th>Age</th> <th>Dose</th> </tr> </thead> <tbody> <tr> <td>children 6 to under 12 years of age</td> <td>10 mL every 4 hours</td> </tr> <tr> <td>children 4 to under 6 years of age</td> <td>5 mL every 4 hours</td> </tr> <tr> <td>children under 4 years of age</td> <td>do not use</td> </tr> </tbody> </table>	Age	Dose	children 6 to under 12 years of age	10 mL every 4 hours	children 4 to under 6 years of age	5 mL every 4 hours	children under 4 years of age	do not use
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<p>*This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Children's Triaminic® Day Time Cold & Cough.</p> <p>TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.</p> <p>PARENTS: Learn about teen medicine abuse www.StopMedicineAbuse.org</p>  <p>Dosing Cup Included</p> <p>DISTRIBUTED BY BETTER LIVING BRANDS LLC P.O. BOX 99, PLEASANTON, CA 94566-0009 1-888-723-3929 www.betterlivingbrandsLLC.com</p> <p>OUR PROMISE QUALITY GUARANTEE 100% GUARANTEED OR YOUR MONEY BACK</p>	<p>Children's Daytime Cold & Cough Relief</p> <p>FOR AGES 4 to 11 YEARS</p> <p>Dextromethorphan HBr 5 mg - Cough Suppressant Phenylephrine HCl 2.5 mg - Nasal Decongestant</p> <p>CHERRY FLAVOR</p> <ul style="list-style-type: none"> Relief of: Cough, stuffy nose Alcohol 0.14% Dosing cup included <p>4 FL OZ (118 mL)</p>	<p>Children's Daytime Cold & Cough Relief</p> <p>FOR AGES 4 to 11 YEARS</p> <p>Dextromethorphan HBr 5 mg - Cough Suppressant Phenylephrine HCl 2.5 mg - Nasal Decongestant</p> <p>CHERRY FLAVOR</p> <ul style="list-style-type: none"> Relief of: Cough, stuffy nose Alcohol 0.14% Dosing cup included <p>4 FL OZ (118 mL)</p>									
<p>S3398 RD19071</p>  <p>3 21130 78208 7</p>  <p>Scan here for more information</p> <p>PLD-G319E FX004144</p> <p>Lot No.: Exp. Date:</p>											

SIGNATURE CARE Children's Daytime Cold & Cough Relief

TRIACTING DAYTIME COLD COUGH CHILDRENS

dextromethorphan hbr, phenylephrine hcl syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-378
Route of Administration	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)	
ALCOHOL (UNII: 3K9958V90M)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
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: 059QF0K00R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-378-04	1 in 1 BOX	05/31/2015	
1		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	05/31/2015	

Labeler - Safeway, Inc. (009137209)

