DIMETAPP COLD AND COUGH AND DIMETAPP NIGHTTIME COLD AND CONGESTION- brompheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride, and diphenhydramine hyrdochloride
Foundation Consumer Brands

Dimetapp® Cold and Cough and Dimetapp® Nighttime Cold and Congestion

Dimetapp®
Cold and Cough

Drug Facts

Active ingredients (in each 10 mL)	***Purposes***
Brompheniramine maleate, 2 mg	Antihistamine
Dextromethorphan HBr, 10 mg	Cough suppressant
Phenylephrine HCl, 5 mg	Nasal decongestant

Uses

- temporarily relieves:
  - nasal congestion
  - runny nose
  - cough
  - sneezing
  - itching of the nose or throat
  - itchy, watery eyes due to hay fever
- temporarily restores freer breathing through the nose

Warnings

Do not use

- to sedate a child or to make a child sleepy
- 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

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- glaucoma
- cough that occurs with too much phlegm (mucus)

- a breathing problem or chronic cough that lasts such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are
- taking any other oral nasal decongestant or stimulant
- taking sedatives or tranquilizers

When using this product
- **do not use more than directed**
- may cause marked drowsiness
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- 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 are accompanied by fever
- cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. 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. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
- do not take more than 6 doses in any 24-hour period
- measure only with dosage cup provided
- keep dosage cup with product
- mL = milliliter

age	dose
adults and children 12 years and over	20 mL every 4 hours
children 6 to under 12 years	10 mL every 4 hours
children under 6 years	do not use

Other information
- each 10 mL contains: **sodium 6 mg**
- store at 20-25°C (68-77°F)

Inactive ingredients

anhydrous citric acid, artificial flavor, FD&C blue no. 1, FD&C red no. 40, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution,

sucralose

Questions or comments?

Call **1-888-594-0828** weekdays 9 AM to 5 PM EST

Dimetapp®
Nighttime Cold and Congestion

Drug Facts

Active ingredients (in each 10 mL)	***Purposes***
Diphenhydramine HCl, 12.5 mg	Antihistamine/cough suppressant
Phenylephrine HCl, 5 mg	Nasal decongestant

Uses

- temporarily relieves:
  - nasal congestion
  - runny nose
  - cough
  - sneezing
  - itching of the nose or throat
  - itchy, watery eyes due to hay fever
- temporarily restores freer breathing through the nose

Warnings

Do not use

- to sedate a child or to make a child sleepy
- 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.
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are

- taking any other oral nasal decongestant or stimulant
- taking sedatives or tranquilizers

When using this product

- **do not use more than directed**
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- 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 are accompanied by fever
- cough lasts more than 7 days, comes back, or is accompanied by fever, rash or persistent headache. 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. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than 6 doses in any 24-hour period
- measure only with dosage cup provided
- keep dosage cup with product
- mL = milliliter

age	dose
adults and children 12 years and over	20 mL every 4 hours
children 6 to under 12 years	10 mL every 4 hours
children under 6 years	do not use

Other information

- each 10 mL contains: **sodium 8 mg**
- store at 20-25°C (68-77°F)
- do not refrigerate

Inactive ingredients

anhydrous citric acid, artificial flavor, FD&C blue no.1, FD&C red no. 40, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose

Questions or comments?

Call **1-888-594-0828** weekdays 9 AM to 5 PM EST

Distributed by:
Foundation Consumer Brands, LLC, Pittsburgh, PA 15212

PRINCIPAL DISPLAY PANEL - Kit Carton

DAYTIME
NIGHTTIME

CHILDREN'S
Dimetapp®

Cold & Cough

BROMPHENIRAMINE MALEATE (Antihistamine)
DEXTROMETHORPHAN HBr (Cough Suppressant)
PHENYLEPHRINE HCl (Nasal Decongestant)

Relieves + comforts:

- ✔ Stuffy, runny nose
- ✔ Itchy, watery eyes
- ✔ Sneezing
- ✔ Cough

Grape Flavor
Alcohol Free

6+
YRS

2 BOTTLES

PHARMACIST
RECOMMENDED

4 FL OZ (118 mL) EACH

Nighttime
Cold &
Congestion

DIPHENHYDRAMINE HCl
(Antihistamine/Cough Suppressant)
PHENYLEPHRINE HCl
(Nasal Decongestant)

Relieves + comforts:

- ✔ Stuffy, runny nose
- ✔ Itchy, watery eyes
- ✔ Sneezing

- ✔ Cough

6+
YRS

Grape Flavor
Alcohol Free

1 BOTTLE

4 FL OZ (118 mL)

12 FL OZ (354 mL) TOTAL

DAYTIME NIGHTTIME

CHILDREN'S Dimetapp®

DAYTIME NIGHTTIME

CHILDREN'S Dimetapp®

Cold & Cough

BROMPHENIRAMINE MALEATE (Antihistamine)
DEXTROMETHORPHAN HBr (Cough Suppressant)
PHENYLEPHRINE HCl (Nasal Decongestant)

Relieves + comforts:
- ✓ Stuffy, runny nose
- ✓ Itchy, watery eyes
- ✓ Sneezing
- ✓ Cough

Grape Flavor Alcohol Free

6+ YRS

PHARMACIST RECOMMENDED

2 BOTTLES

4 FL OZ (118 mL) EACH

Nighttime Cold & Congestion

DIPHENHYDRAMINE HCl (Antihistamine/Cough Suppressant)
PHENYLEPHRINE HCl (Nasal Decongestant)

Relieves + comforts:
- ✓ Stuffy, runny nose
- ✓ Itchy, watery eyes
- ✓ Sneezing
- ✓ Cough

6+ YRS

Grape Flavor Alcohol Free

1 BOTTLE

4 FL OZ (118 mL)

12 FL OZ (354 mL) TOTAL

TM

FPO

8 50026 66007 4

No print/No varnish
Lot & Exp date

CHILDREN'S Dimetapp®

Cold & Cough

Nighttime Cold & Congestion

Dosage Cup Provided

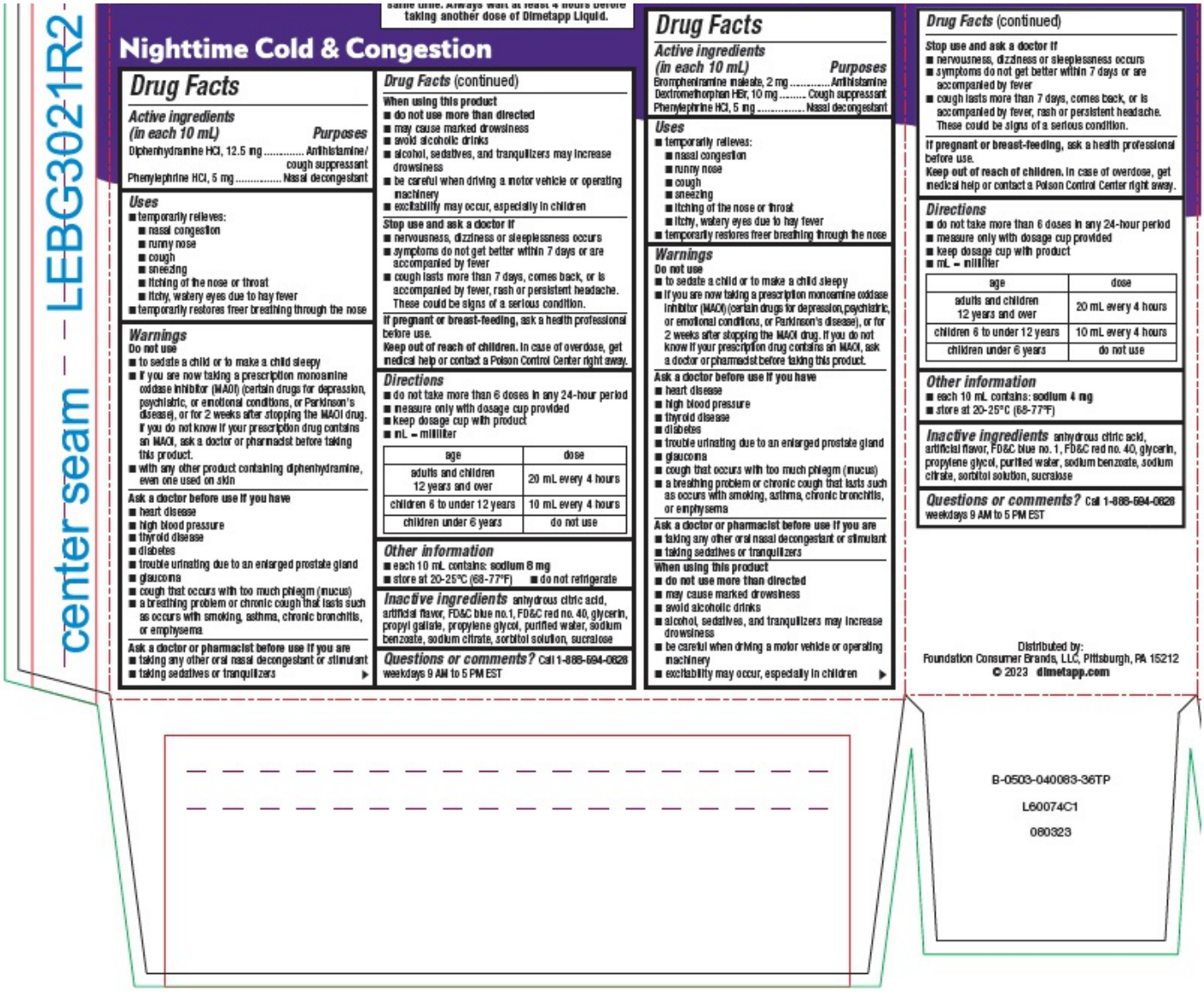
PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

Tamper Evident: do not use if neckband printed with "sealed for your protection" is torn or missing.

Do not take Dimetapp® Cold & Cough and Dimetapp® Nighttime Cold & Congestion at the same time. Always wait at least 4 hours before

Cold & Cough

Cold & Cough



DIMETAPP COLD AND COUGH AND DIMETAPP NIGHTTIME COLD AND CONGESTION

brompheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride, and diphenhydramine hyrdochloride kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80070-360

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80070-360-12	1 in 1 CARTON	09/15/2021	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity

Part 1	2 BOTTLE	236 mL
Part 2	1 BOTTLE	118 mL

Part 1 of 2

DIMETAPP COLD AND COUGH

brompheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride elixir

Product Information

Item Code (Source)	NDC:80070-310
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BROMPHENIRAMINE MALEATE (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	1 mg in 5 mL
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

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:80070-310-04	1 in 1 CARTON		
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 drug	M012	09/15/2021	

Part 2 of 2

DIMETAPP NIGHTTIME COLD AND CONGESTION

diphenhydramine hydrochloride and phenylephrine hydrochloride solution

Product Information

Item Code (Source)	NDC:80070-340
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

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:80070-340-04	1 in 1 CARTON		
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 drug	M012	09/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M012	09/15/2021	

Labeler - Foundation Consumer Brands (117603632)

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