

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

-----  
**Dimetapp Cold and Cough and Nighttime Cold and Congestion**

**Dimetapp®  
Nighttime Cold and Congestion**

***Drug Facts***

<b><i>Active ingredients (in each 10 mL)</i></b>	<b><i>Purposes</i></b>
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 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 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

<b>age</b>	<b>dose</b>
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

## Dimetapp® Cold and Cough

### Drug Facts

<b>Active ingredients (in each 10 mL)</b>	<b>Purposes</b>
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 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

<b>age</b>	<b>dose</b>
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 4 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

Distributed by:

Foundation Consumer Brands, LLC, Pittsburgh, PA 15212

### **PRINCIPAL DISPLAY PANEL - Kit Carton**

DAYTIME

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

6+  
YRS

Grape Flavor  
Alcohol Free

1 BOTTLE

4 FL OZ (118 mL)

8 FL OZ (236 mL) TOTAL

NIGHTTIME

Nighttime  
Cold &  
Congestion

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

Relieves + comforts:

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

✓ Cough

PHARMACIST  
RECOMMENDED

6+  
YRS

Grape Flavor  
Alcohol Free

1 BOTTLE

4 FL OZ (118 mL)

DAYTIME

NIGHTTIME

CHILDREN'S  
**Dimetapp**<sup>®</sup>

DAYTIME

NIGHTTIME

CHILDREN'S  
**Dimetapp**<sup>®</sup>

**Cold & Cough**

**Nighttime Cold & Congestion**

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

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

**Relieves + comforts:**

- ✓ **Stuffy, runny nose**
- ✓ **Itchy, watery eyes**
- ✓ **Sneezing**
- ✓ **Cough**

**Relieves + comforts:**

- ✓ **Stuffy, runny nose**
- ✓ **Itchy, watery eyes**
- ✓ **Sneezing**
- ✓ **Cough**

**6+**  
**YRS**



**Grape Flavor**  
**Alcohol Free**

**1 BOTTLE**

4 FL OZ (118 mL)



8 FL OZ (236 mL) TOTAL



**6+**  
**YRS**



**Grape Flavor**  
**Alcohol Free**

**1 BOTTLE**

4 FL OZ (118 mL)

**Cold & Cough** (continued)

**Drug Facts** (continued)

**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 4 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

**PARENTS:**

Learn about teen medicine abuse

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

Distributed by:  
Foundation Consumer Brands, LLC, Pittsburgh, PA 15212  
© 2023 [dimetapp.com](http://dimetapp.com)

B-0503-040/083-36

L60067C1

080223



No print/No varnish  
Lot & Exp date

side seam  
LEBG3007K3

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

## Nighttime Cold & Congestion

### Drug Facts

#### Active ingredients

(in each 10 mL)

Diphenhydramine HCl, 12.5 mg ..... Antihistamine/  
cough suppressant  
Phenylephrine HCl, 5 mg ..... Nasal decongestant

#### Purposes

#### 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 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

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

## Nighttime Cold & Congestion (continued)

### Drug Facts (continued)

#### 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

## Cold & Cough

### Drug Facts

#### Active ingredients

(in each 10 mL)

Brompheniramine maleate, 2 mg ..... Antihistamine  
Dextromethorphan HBr, 10 mg ..... Cough suppressant  
Phenylephrine HCl, 5 mg ..... Nasal decongestant

#### Purposes

#### 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 drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children



# DIMETAPP COLD AND COUGH AND NIGHTTIME COLD AND CONGESTION

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

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80070-350
---------------------	----------------	---------------------------	---------------

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80070-350-08	1 in 1 CARTON	09/15/2021	

## Quantity of Parts

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

## Part 1 of 2

### DIMETAPP NIGHTTIME COLD AND CONGESTION

diphenhydramine hydrochloride and phenylephrine hydrochloride solution

## Product Information

<b>Item Code (Source)</b>	NDC:80070-340
---------------------------	---------------

<b>Route of Administration</b>	ORAL
--------------------------------	------

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)	

<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

### Product Characteristics

<b>Color</b>	PURPLE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

### 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	

## Part 2 of 2

### DIMETAPP COLD AND COUGH

brompheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride elixir

### Product Information

<b>Item Code (Source)</b>	NDC:80070-310
<b>Route of Administration</b>	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BROMPHENIRAMINE MALEATE</b> (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	1 mg in 5 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL

<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL
---	-----------------------------	-------------------

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

### Product Characteristics

<b>Color</b>	PURPLE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

### 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	

### 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)

