# VICKS CHILDRENS COUGH CONGESTION- dextromethorphan hydrobromide, diphenhydramine hcl, guaifenesin, phenylephrine hydrochloride The Procter & Gamble Manufacturing Company

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# Vicks <sup>®</sup> children's Cough Congestion FREE of Convenience Pack

Vicks children's Cough Congestion (Night)

### Active ingredients (in each 15 mL)

Diphenhydramine HCl 12.5 mg
Phenylephrine HCl 5 mg

### **Purpose**

Antihistamine/Cough suppressant Nasal decongestant

#### Uses

temporarily relieves common cold symptoms:

- nasal congestion
- runny nose & sneezing
- cough due to minor throat and bronchial irritation

# **Warnings**

#### Do not use

- with any other product containing diphenhydramine, even one used on skin
- 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
- glaucoma
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, or emphysema

a sodium-restricted diet

### Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

# When using this product

- do not use more than directed.
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

#### Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- 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.

**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**

- take only as directed
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children
12 yrs & over
children 6 to under
12 yrs
children 4 to under do not use unless
6 yrs
children under 4
yrs
do not use

#### Other information

- each 15 mL contains:sodium 44 mg
- Store at no greater than 25°C.

#### Inactive ingredients

anhydrous citric acid, flavor, glycerin, polysorbate 20, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose

#### **Questions?**

1-800-362-1683

**DIST. BY: PROCTER & GAMBLE, CINCINNATI, OH 45202** 

Made in Canada

VICKS® childrens Cough Congestion(Day)

#### Active ingredients (in each 15 mL)

Dextromethorphan HBr 10 mg Guaifenesin 200 mg

Phenylephrine HCl 5 mg

### **Purpose**

Cough suppressant Expectorant

Nasal decongestant

#### Uses

temporarily relieves common cold symptoms:

- nasal congestion
- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

# Warnings

#### Do not use

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 enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- a sodium-restricted diet

# When using this product, do not use more than directed.

#### Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- 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.

**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**

- take only as directed
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs &	30 mL every 4
over	hrs
children 6 to under 12 yrs	15 mL every 4
criliaren o to under 12 yrs	hrs
children 4 to under 6 yrs	
children under 4 yrs	do not use

#### Other information

- each 15 mL contains: sodium 44 mg
- store at no greater than 25°C

# **Inactive ingredients**

anhydrous citric acid, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose

# **Questions?**

#### 1-800-362-1683

TAMPER EVIDENT: Do not use if printed safety seal under cap is missing or damaged

**DIST. BY: PROCTER & GAMBLE, CINCINNATI, OH 45202** 

Made in Canada

#### PRINCIPAL DISPLAY PANEL - Kit Carton

DAY & NIGHT PACK

children's Cough Congestion

Phenylephrine HCl - nasal decongestant

Dextromethorphan HBr - cough suppressant

Guaifenesin - expectorant

Non-Drowsy

FREE of:

Artificial Dyes & Flavors,

High Fructose Corn Syrup & Alcohol

- Cough
- Chest congestion
- Stuffy nose

Ages 4+

children's Cough Congestion Night

Phenylephrine HCl - nasal decongestant

Diphenhydramine HCI - antihistamine/cough suppressant

Nighttime

FREE of:

Artificial Dyes & Flavors,

High Fructose Corn Syrup & Alcohol

- Cough
- Runny nose
- Stuffy nose
- Sneezing

Ages 6+

2 BOTTLES - 6 FL OZ (177 mL) EACH; TOTAL 12 FL OZ (354 mL)





# children's congestion

Phenylephrine HCI - nasal decongestant Dextromethorphan HBr - cough suppressant Guaifenesin - expectorant

Phenylephrine HCI - nasal decongestant Diphenhydramine HCI -antihistamine/cough suppressant

ongestion

children's

Nighttime

Artificial Dyes & Flavors, High Fructose Corn Syrup & Alcohol

Cough

Non-Drowsy

- Chest congestion
- Stuffy nose

Ages 4+



- Cough
- Runny nose Stuffy nose
- Sneezing

Ages 6+



#### Children's Cough Congestion Night

#### Drug Facts (continued) Directions • take only as directed only use the dose cup provided do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over 30 mL every 4 hrs children 6 to under 12 yrs 15 mL every 4 hrs children 4 to under 6 yrs do not use unless directed by a doctor children under 4 vrs do not use

#### Other information each 15 mL contains: sodium 44 mg Store at no greater than 25°C.

Inactive ingredients anhydrous citric acid, flavor, glycerin, polysorbate 20, propytene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution,

Questions? 1-800-362-1683

TAMPER EVIDENT: Do not use if printed DIST. BY: PROCTER & GAMBLE, CINCINNATI, OH 45202

Children's Cough Congestion Day

Inactive ingredients anhydrous citric acid,

flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride sodium citrate, sorbitol solution, sucralose

**Drug Facts** (continued)

Store at no greater than 25°C.

Questions? 1-800-362-1683

each 15 mL contains: sodium 44 mg

Other information

Made in Canada

www.pg.com/ patents www.vicks.com

P&G





# 2 BOTTLES - 6 FL OZ (177 mL) EACH; TOTAL 12 FL OZ (354 mL)

Children's Cough Congestion Night

Children's Cough Congestion Day

#### Active ingredients (in each 15 mL) Purpose Diphenhydramine HCl 12.5 Phenylephrine HCl 5 mg ... ine HCl 12.5 mg ..... Antihistamine/Cough supp Uses temporarily relieves common cold symptoms:

nasal congestion • runny nose & sneezing
 cough due to minor throat & bronchial irritation

#### Warnings Do not use

- Do not use

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

   if you are now taking a prescription monoamine coidses inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after slooping the MAOI drug. If you do not know if your prescription drug contain an MAOI, ask a doctor or pharmaciet before taking this product.

Ask a doctor before use if you have • heart di

- high blood pressure thyroid disease diabetes diabetes glaucoma trouble urinating due to enlarged prostate gland cough that occurs with too much phiegm (micros) a breathing problem or chronic cough that lasts or occurs with smoking, asthma or emphysema a sodium-restricted diet

Ask a doctor or pharmacist before use if you are taking sedatives

When using this product • do not use more than directed. excitability may occur, especially in children
 marked drowsiness may occur
 alcohol, sedatives, and tranquilizers may increase drowsiness

- avoid alcoholic drinks · be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if • you get nervous, dizzy or sleepless • 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

ver, 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.

#### Drug Facts

Active ingredients (in each 15 mL)	Purpose
	n suppressant
Gualfenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	decongestant

Uses temporarily relieves common cold symptoms:

nasal congestion • cough due to minor throat & bronchial irritation

helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

#### Warnings

Do not use if you are now taking a prescription monoamine coddase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotiona conditions, or Parkinson's disease), or for 2 weeks after stopping the conditions, or rankinson's disease,, or for 2 weeks after supping 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 dis

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema a sodium-restricted diet

When using this product, do not use more than directed.

Stop use and ask a doctor if • you get nervous, dizzy or sleepless • 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

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use. Kaep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions • take only as directed • only use the dose cup provided • do not exceed 4 doses per 24 hrs adults & children 12 yrs & over | 30 mL every 4 hrs

15 mL every 4 hrs children 6 to under 12 yrs children 4 to under 6 yrs 7.5 mL every 4 hrs children under 4 yrs do not use

# VICKS CHILDRENS COUGH CONGESTION

dextromethorphan hydrobromide, diphenhydramine hcl, guaifenesin, phenylephrine hydrochloride kit

#### **Product Information**

Product Type HUMAN OTC DRUG	Item Code (Source)	NDC:69423-997
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l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:69423-997- 12	1 in 1 PACKAGE; Type 0: Not a Combination Product	07/09/2019	

Quant	Quantity of Parts		
Part #	Package Quantity	Total Product Quantity	
Part 1	1 BOTTLE, PLASTIC	177 mL	
Part 2	1 BOTTLE, PLASTIC	177 mL	

# Part 1 of 2

# **VICKS CHILDRENS COUGH CONGESTION**

phenylephrine hcl, dextromethorphan hbr, guaifenesin liquid

Product Information	
Item Code (Source)	NDC:69423-982
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

Inactive Ingredients		
Ingredient Name Strength		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3Z D4)		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		

Product Characteristics		
Color	white (Clear)	Score
Shape		Size
Flavor	STRAWBERRY	Imprint Code
Contains		

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:69423- 982-06	177 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 Drug	M012	07/09/2021	

# Part 2 of 2

# **VICKS CHILDRENS COUGH CONGESTION NIGHT**

phenylephrine hydrochloride and diphenhydramine hydrochloride liquid

Product Information	
Item Code (Source)	NDC:37000-712
Route of Administration	ORAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL	
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 15 mL	

Inactive Ingredients		
Ingredient Name	Strength	
POLYSORBATE 20 (UNII: 7T1F30V5YH)		
WATER (UNII: 059QF0KO0R)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		

SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUCRALOSE (UNII: 96K6UQ3Z D4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics				
Color	white (Clear)	Score		
Shape		Size		
Flavor	GRAPE	Imprint Code		
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:37000- 712-06	177 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 Drug	M012	07/09/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/09/2019	

# **Labeler -** The Procter & Gamble Manufacturing Company (004238200)

Revised: 10/2023 The Procter & Gamble Manufacturing Company