

DIMETAPP MULTI-SYMPTOM COLD AND FLU- acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride solution

Foundation Consumer Brands

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Dimetapp® Multi-Symptom Cold and Flu

Drug Facts

Active ingredients (in each 10 mL)	Purposes
Acetaminophen, 320 mg	Pain reliever/fever reducer
Diphenhydramine HCl, 12.5 mg	Antihistamine/cough suppressant
Phenylephrine HCl, 5 mg	Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
 - minor aches and pains
 - headache
 - nasal congestion
 - sore throat
 - cough
 - runny nose
 - itching of the nose or throat
 - sneezing
- temporarily reduces fever
- temporarily restores freer breathing through the nose

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 6 doses in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product.

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters

- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- to sedate a child or to make a child sleepy
- in a child under 6 years of age
- 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 drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen ask a doctor or pharmacist.
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if user has

- liver disease
- 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 user is

- taking the blood thinning drug warfarin
- 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
- pain, cough, or nasal congestion gets worse or lasts more than 5 days (children) or 7

days (adults)

- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with fever, rash or headache that lasts. 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. Prompt medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

Directions

- do not exceed recommended dosage. Taking more than the recommended dose (overdose) may cause serious liver damage.
- 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 do not take more than 6 doses in any 24-hour period
children 6 to 12 years	10 mL every 4 hours do not give more than 5 doses in any 24-hour period
children under 6 years	do not use

Other information

- each 10 mL contains: **sodium 7 mg and potassium 6 mg**
- store at 20-25°C (68-77°F)
- read and keep carton

Inactive ingredients

anhydrous citric acid, artificial flavor, edetate disodium, FD&C red no. 40, glycerin, menthol, polyethylene glycol, 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 - 118 mL Bottle Carton

CHILDREN'S
Dimetapp®

ACETAMINOPHEN (Pain Reliever/Fever Reducer)
DIPHENHYDRAMINE HCl (Antihistamine/Cough Suppressant)
PHENYLEPHRINE HCl (Nasal Decongestant)

PHARMACIST
RECOMMENDED

Multi-
Symptom
Cold & Flu

Relieves + comforts:

- ✓ Fever
- ✓ Head & body aches
- ✓ Cough
- ✓ Stuffy, runny nose
- ✓ Sneezing
- ✓ Sore throat

6+
YRS

4 FL OZ
(118 mL)

Red Grape Flavor • Alcohol Free

CHILDREN'S Dimetapp®

ACETAMINOPHEN (Pain Reliever/Fever Reducer)
DIPHENHYDRAMINE HCl (Antihistamine/Cough Suppressant)
PHENYLEPHRINE HCl (Nasal Decongestant)

**Multi-Symptom
Cold & Flu**

CHILDREN'S Dimetapp®

ACETAMINOPHEN (Pain Reliever/Fever Reducer)
DIPHENHYDRAMINE HCl (Antihistamine/Cough Suppressant)
PHENYLEPHRINE HCl (Nasal Decongestant)



**Multi-Symptom
Cold & Flu**

Relieves + comforts:

- ✓ **Fever**
- ✓ **Cough**
- ✓ **Sneezing**
- ✓ **Head & body aches**
- ✓ **Stuffy, runny nose**
- ✓ **Sore throat**

**6+
YRS**



Drug Facts

Active ingredients (in each 10 mL)

Purposes

Acetaminophen, 320 mg	Pain reliever/fever reducer
Diphenhydramine HCl, 12.5 mg	Antihistamine/ cough suppressant
Phenylephrine HCl, 5 mg	Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
 - minor aches and pains
 - nasal congestion
 - cough
 - itching of the nose or throat
 - headache
 - sore throat
 - runny nose
 - sneezing
- temporarily reduces fever
- temporarily restores freer breathing through the nose

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 6 doses in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product.

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
 - blisters
 - rash
- If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- to sedate a child or to make a child sleepy
- in a child under 6 years of age
- 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 drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen ask a doctor or pharmacist.
- with any other product containing diphenhydramine,

4 FL OZ
(118 mL)

Red Grape Flavor • Alcohol Free

even one used on skin

No print/No varnish
Lot & Exp date

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

CHILDREN'S Dimetapp®

Drug Facts (continued)

Ask a doctor before use if user has

- liver disease
- 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 user is

- taking the blood thinning drug warfarin
- 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

CHILDREN'S Dimetapp®

Drug Facts (continued)

age	dose
adults and children 12 years and over	20 mL every 4 hours do not take more than 6 doses in any 24-hour period
children 6 to under 12 years	10 mL every 4 hours do not give more than 5 doses in any 24-hour period
children under 6 years	do not use

Other information

- each 10 mL contains: sodium 7 mg and potassium 6 mg
- store at 20-25°C (68-77°F) ■ read and keep carton

Inactive ingredients anhydrous citric acid, artificial flavor, edetate disodium, FD&C red no. 40, glycerin, menthol, polyethylene glycol, 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

EBG3018R1
center seam



Dosage Cup

- nervousness, dizziness or sleeplessness occurs
- pain, cough, or nasal congestion gets worse or lasts more than 5 days (children) or 7 days (adults)
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with fever, rash or headache that lasts. 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. Prompt medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

Directions

- do not exceed recommended dosage. Taking more than the recommended dose (overdose) may cause serious liver damage.
- measure only with dosage cup provided
- keep dosage cup with product ■ mL = milliliter ▶



Provided

Distributed by:
Foundation Consumer Brands, LLC, Pittsburgh, PA 15212
© 2023 dimetapp.com



|B-0503-085-36 ORG

60050C1

072023

DIMETAPP MULTI-SYMPATOM COLD AND FLU

acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80070-330
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	320 mg in 10 mL
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYL GALLATE (UNII: 8D45NN7V92)	
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	RED	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80070-330-04	1 in 1 CARTON	09/15/2021	
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
UNAPPROVED DRUG OTHER		09/15/2021	

Labeler - Foundation Consumer Brands (117603632)

Revised: 11/2023

Foundation Consumer Brands