

**DIMETAPP MULTI-SYMPATOM COLD AND FLU- acetaminophen,  
diphenhydramine hydrochloride solution**  
Foundation Consumer Healthcare

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**Dimetapp®**  
**Multi-Symptom Cold and Flu**

**Drug Facts**

<b>Active ingredients (in each 10 mL)</b>	<b>Purposes</b>
Acetaminophen, 320 mg	Pain reliever/fever reducer
Diphenhydramine HCl, 12.5 mg	Antihistamine/cough suppressant

**Uses**

- temporarily relieves these common cold and flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - cough
  - runny nose
  - sneezing
  - temporarily alleviates the intensity of coughing
- temporarily reduces fever

**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
- 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
- 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 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**

- pain or cough 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

<b>age</b>	<b>dose</b>
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 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 Healthcare, LLC, Pittsburgh, PA 15212

### **PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton**

NEW FORMULA

CHILDREN'S  
Dimetapp®

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

PHARMACIST  
RECOMMENDED

Multi-  
Symptom  
Cold & Flu

Relieves + comforts:

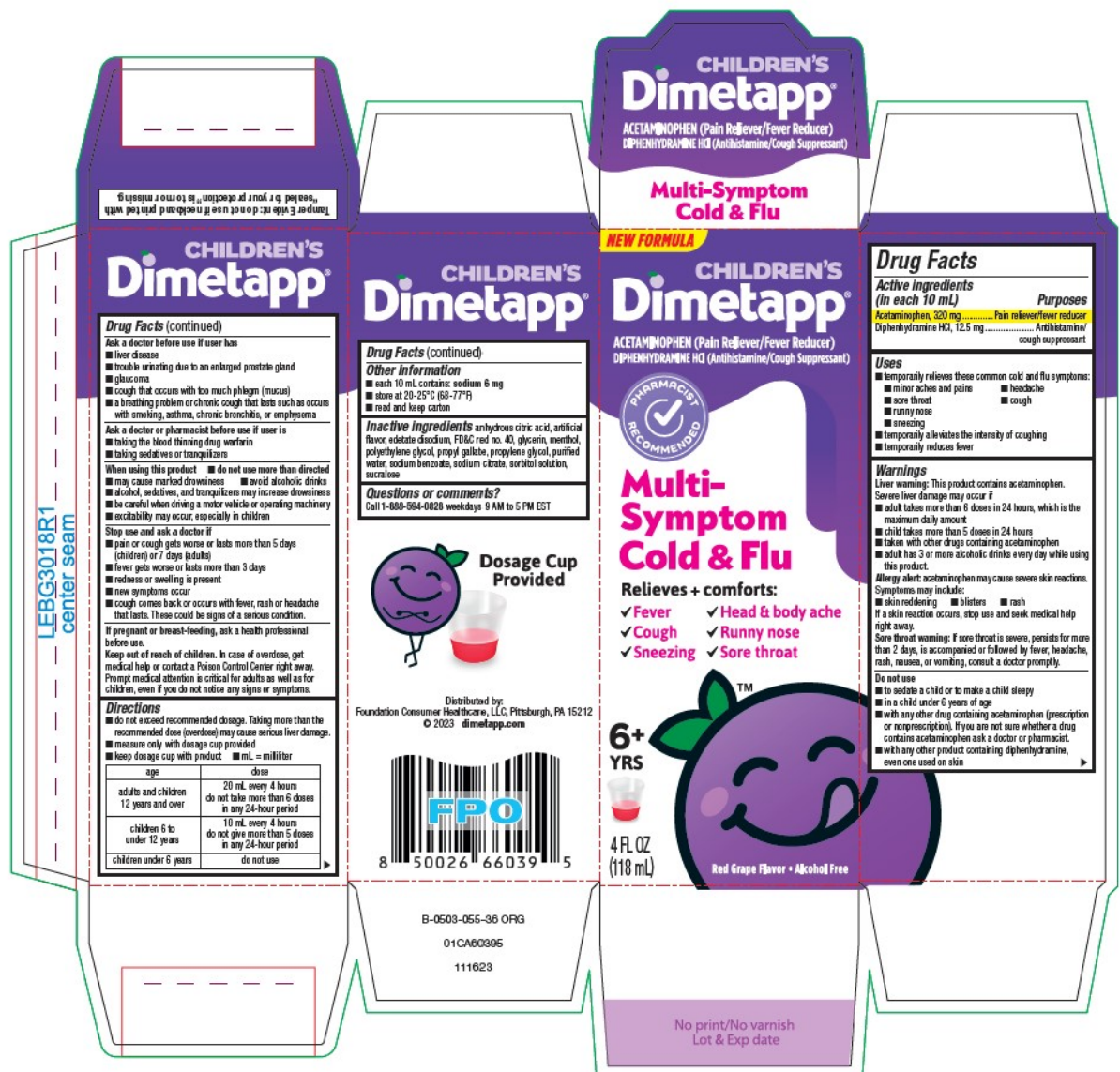
- Fever

- Head & body aches
- Cough
- Runny nose
- Sneezing
- Sore throat

6+  
YRS

4 FL OZ  
(118 mL)

Red Grape Flavor • Alcohol Free



## DIMETAPP MULTI-SYMPATOM COLD AND FLU

acetaminophen, diphenhydramine hydrochloride solution

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69536-335

<b>Route of Administration</b>	ORAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	320 mg in 10 mL
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 10 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<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>	red	<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:69536-335-04	1 in 1 CARTON	06/01/2024	
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	06/01/2024	

Revised: 6/2024

Foundation Consumer Healthcare