

**CHILDRENS COUGH AND COLD- chlorpheniramine maleate, dextrometorphan hbr liquid**

**FAMILY DOLLAR SERVICES INC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Family Dollar Children's Cough & Cold**

**DRUG FACTS**

**Active ingredients (in each 10 mL)**

Chlorpheniramine maleate, USP 2 mg

Dextromethorphan HBr, USP 15 mg

**Purposes**

Antihistamine

Cough suppressant

**Uses**

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itching of the nose or throat

**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**

- trouble urinating due to an enlarged prostate gland
- glaucoma
- a 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 sedatives or tranquilizers

**When using this product**

- **do not use more than directed**
- marked drowsiness may occur
- 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**

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 at 1-800-222-1222.

**Directions**

- measure only with dosing cup provided
- keep dosing cup with product
- mL = milliliter
- do not take more than 4 doses in any 24-hour period

| <b>age</b>                             | <b>dose</b>         |
|--|---------------------|
| Children under 6 years                 | do not use          |
| children 6 to under 12 years           | 10 mL every 6 hours |
| adults and children 12 years and older | 20 mL every 6 hours |

**Other information**

- each 10 mL contains: **sodium 7 mg**
- store at room temperature. Do not refrigerate.

## **Inactive ingredients**

Anhydrous citric acid, FD&C red no. 40, Glycerin, lactic acid, natural and artificial flavors, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose

## **QUESTIONS OR COMMENTS?**

**1-866-467-2748**

## **Principal Display of Packaging**

Compare to the active ingredients in Children's Robitussin® Cough & Cold Long-Acting\*

**NDC 55319-754-04**

## **CHILDREN'S**

## **COUGH & COLD**

Chlorpheniramine Maleate USP 2 mg (Antihistamine)

Dextromethorphan HBr, USP 15 mg (Cough Suppressant)

Long-Acting

Relieves:

- Cough up to 8 hours
  - Runny nose
  - No Added alcohol
- For Ages 6 & Over

Fruit Punch Flavor

Naturally and Artificially Flavored

4 FL OZ (118 mL)

**IMPORTANT:** Keep this carton for future reference on full labeling

Distributed by:



## CHILDRENS COUGH AND COLD

chlorpheniramine maleate, dextrometorphan hbr liquid

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:55319-754 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength             | Strength          |
|--|-------------------------------|-------------------|
| <b>chlorpheniramine maleate</b> (UNII: V1Q0O9OJ9Z) (chlorpheniramine - UNII:3U6IO1965U)      | chlorpheniramine maleate      | 2 mg<br>in 10 mL  |
| <b>dextromethorphan hydrobromide</b> (UNII: 9D2RTI9KYH) (dextromethorphan - UNII:7355X3ROTS) | dextromethorphan hydrobromide | 15 mg<br>in 10 mL |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)            |          |
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)              |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                         |          |
| <b>LACTIC ACID, UNSPECIFIED FORM</b> (UNII: 33X04XA5AT)    |          |
| <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>   | FRUIT PUNCH | <b>Imprint Code</b> |  |
| <b>Contains</b> |             |                     |  |

### Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:55319-754-04 | 1 in 1 CARTON   | 05/08/2023           |                    |
| 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 final | part341                                  | 05/08/2023           |                    |

**Labeler** - FAMILY DOLLAR SERVICES INC (024472631)