

**ZODRYL DAC 80 - chlorpheniramine maleate, codeine phosphate and pseudoephedrine hydrochloride suspension**

**CodaDose 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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**ZODRYL DAC 80 – chlorpheniramine maleate, codeine phosphate, and pseudoephedrine hydrochloride suspension**

**OTC - ACTIVE INGREDIENT**

Chlorpheniramine Maleate 0.200 mg/1mL: antihistamine; Codeine Phosphate 1 mg/1mL: cough suppressant; Pseudoephedrine Hydrochloride 3 mg/1mL: decongestant

**PURPOSE**

Temporarily relieves: cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants; the intensity of coughing; the impulse to cough to help you go to sleep; temporarily relieves nasal congestion due to a cold; temporarily restores freer breathing through the nose; temporarily decreases runny nose and reduces sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever or other upper respiratory allergies

Warnings

**OTC - DO NOT USE**

in children who have chronic pulmonary disease, shortness of breath, or who are taking other drugs unless directed by a doctor; for persistent or chronic cough such as occurs with asthma or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor; if taking a monoamine oxidase inhibitor (MAOI)

**OTC - ASK DOCTOR**

if your child has glaucoma, a breathing problem such as emphysema or chronic bronchitis, heart disease, high blood pressure, thyroid disease, diabetes.

**OTC - ASK DOCTOR/PHARMACIST SECTION**

if you or your child are taking sedatives or tranquilizers; if you or your child are taking prescription MAOI (certain drugs for depression, psychiatric, or emotional conditions), or for 2 weeks after stopping the MAOI drug.

**OTC - WHEN USING THIS PRODUCT**

do not exceed recommended dosage; may cause or aggravate constipation; may cause excitability in children; may cause drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect

**OTC - STOP USE AND ASK A DOCTOR IF**

cough persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent

headache. These could be signs of a serious condition.

## OTC - KEEP THESE AND ALL DRUGS OUT OF REACH OF CHILDREN

In case of overdose, seek professional assistance for contact a Poison Control Center immediately.

Directions:

- Take every 4-6 hours
- Use only with enclosed calibrated oral dispenser
- Do not take more than 4 doses in 24 hours or as directed by a doctor

Children 6 to under 12 years of age: 10 mL

Other information store at controlled room temperature 20°-25°C (68°-77°F).

## INACTIVE INGREDIENT

citric acid, FD&C blue#1, galloquinat, glycerin, grape flavor, magnesium aluminometasilicate, methylparaben, purified water, sodium citrate dihydrate, sucralose, xanthan gum

## OTC – QUESTIONS SECTION

Call 1-866-574-8861 24 hours a day, 7 days a week.

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

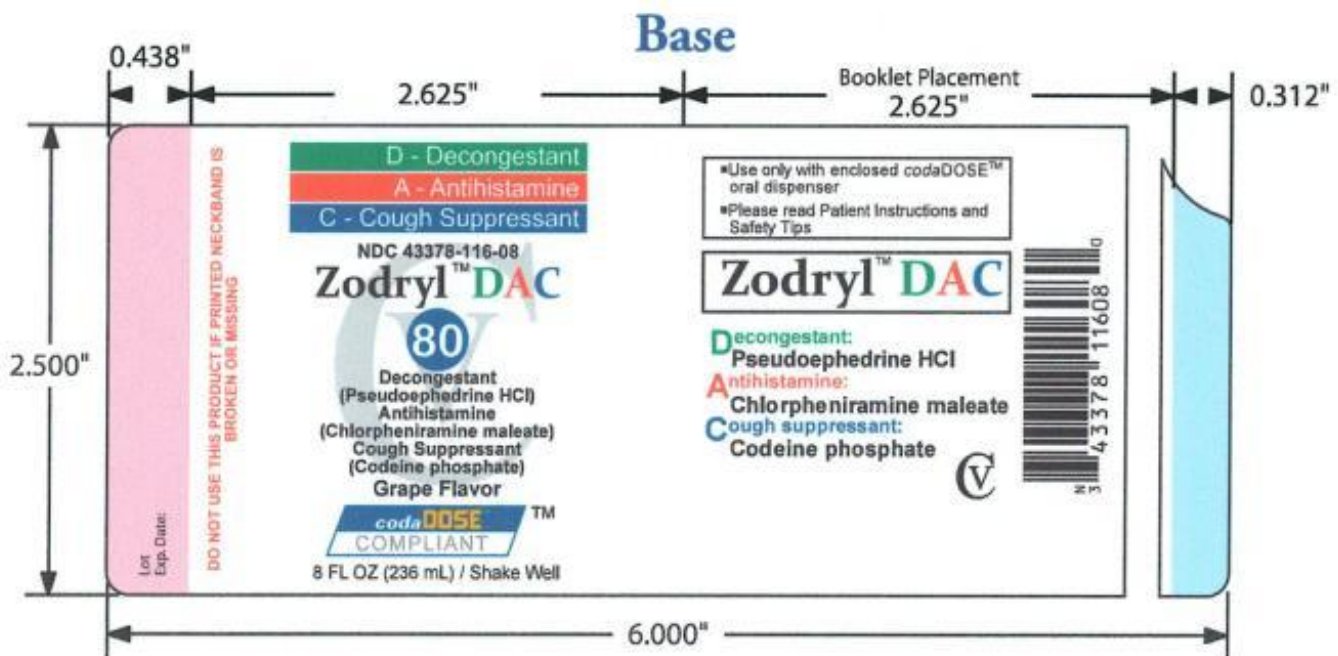


Figure 1. Primary Label- Front Page

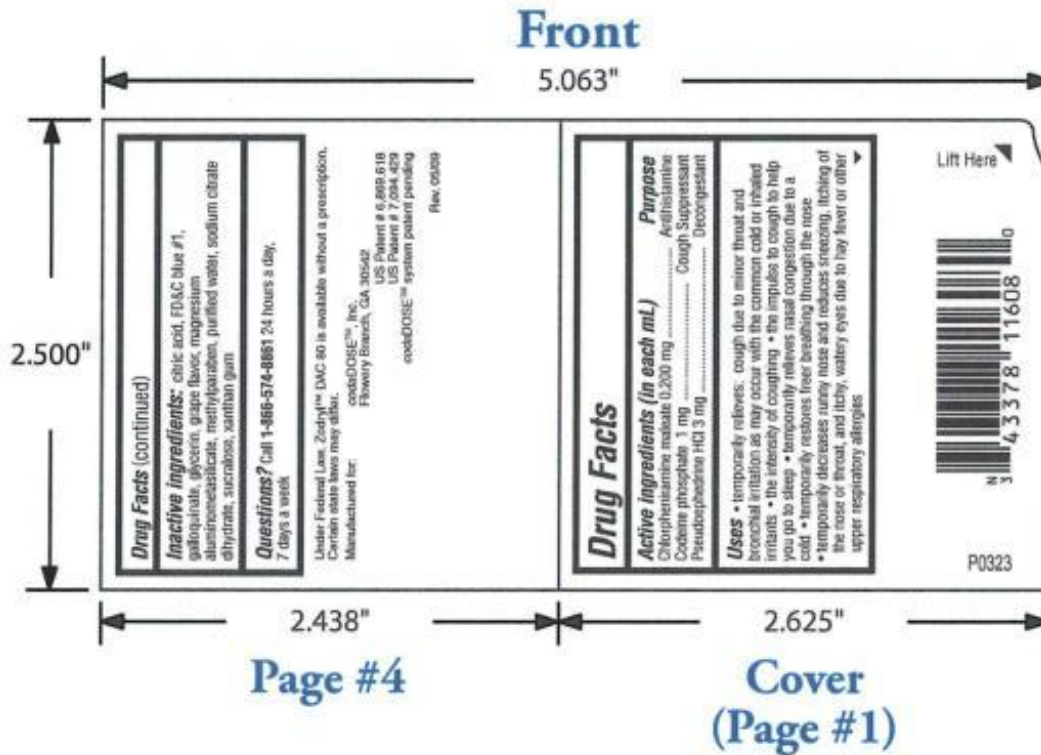


Figure 2. Primary Label – Second Page

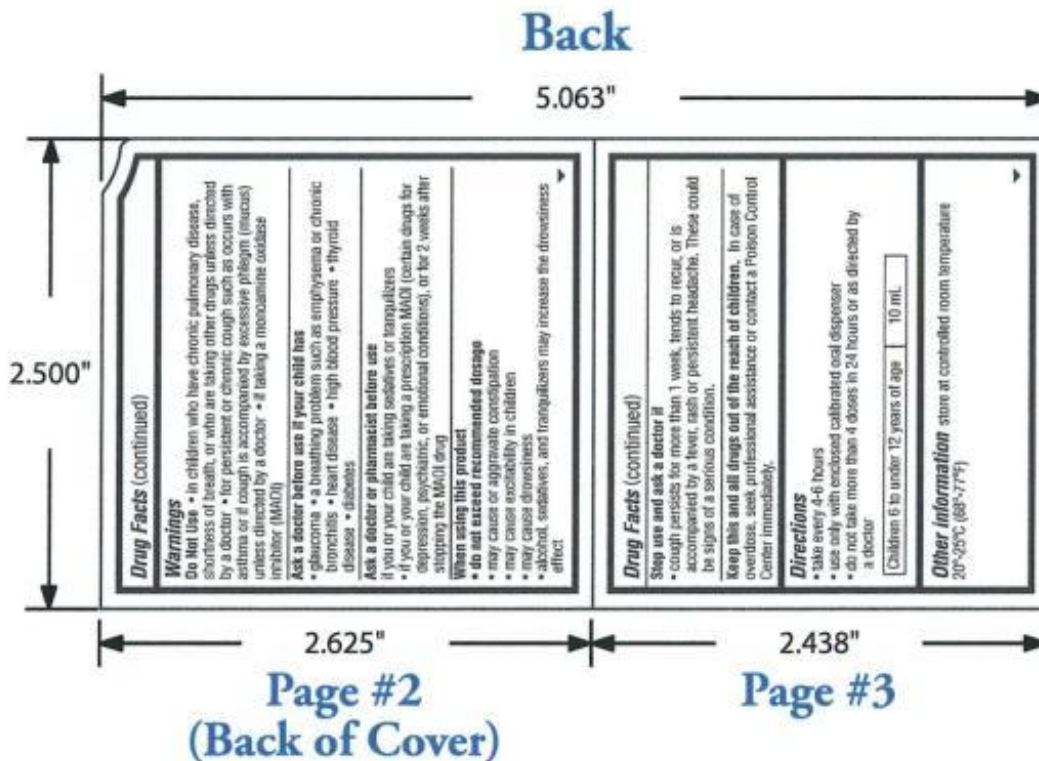


Figure 3. Primary Label – Last Page

**ZODRYL DAC 80**

chlorpheniramine maleate, codeine phosphate and pseudoephedrine hydrochloride suspension

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43378-116
<b>Route of Administration</b>	ORAL	<b>DEA Schedule</b>	CV

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg in 10 mL
<b>CODEINE PHOSPHATE</b> (UNII: GSL05Y1MN6) (CODEINE - UNII:Q830PW7520)	CODEINE PHOSPHATE	10 mg in 10 mL
<b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg in 10 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)	
<b>TANNIC ACID</b> (UNII: 28F9E0DJY6)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	

### Product Characteristics

<b>Color</b>	blue	<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:43378-116-08	236 mL in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2040	

**Labeler** - CodaDose Inc. (831355115)

**Registrant** - Gorbec Pharmaceutical Services Inc (791919678)

## Establishment

Name	Address	ID/FEI	Business Operations
Gorbec Pharmaceutical Services Inc.		79 19 196 78	manufacture

Revised: 9/2009

CodaDose Inc.