**ZODRYL DAC 35 - 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 35 – chlorpheniramine maleate, codeine phosphate, and pseudoephedrine hydrochloride suspension**

## OTC - ACTIVE INGREDIENT

Chlorpheniramine Maleate 0.250 mg/1mL: antihistamine; Codeine Phosphate 1 mg/1mL: cough suppressant; Pseudoephedrine Hydrochloride 3.750 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 2 to under 6 years of age: ask a doctor

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

**INACTIVE INGREDIENT**

citric acid, FD&C blue#1, galloquinate, 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**

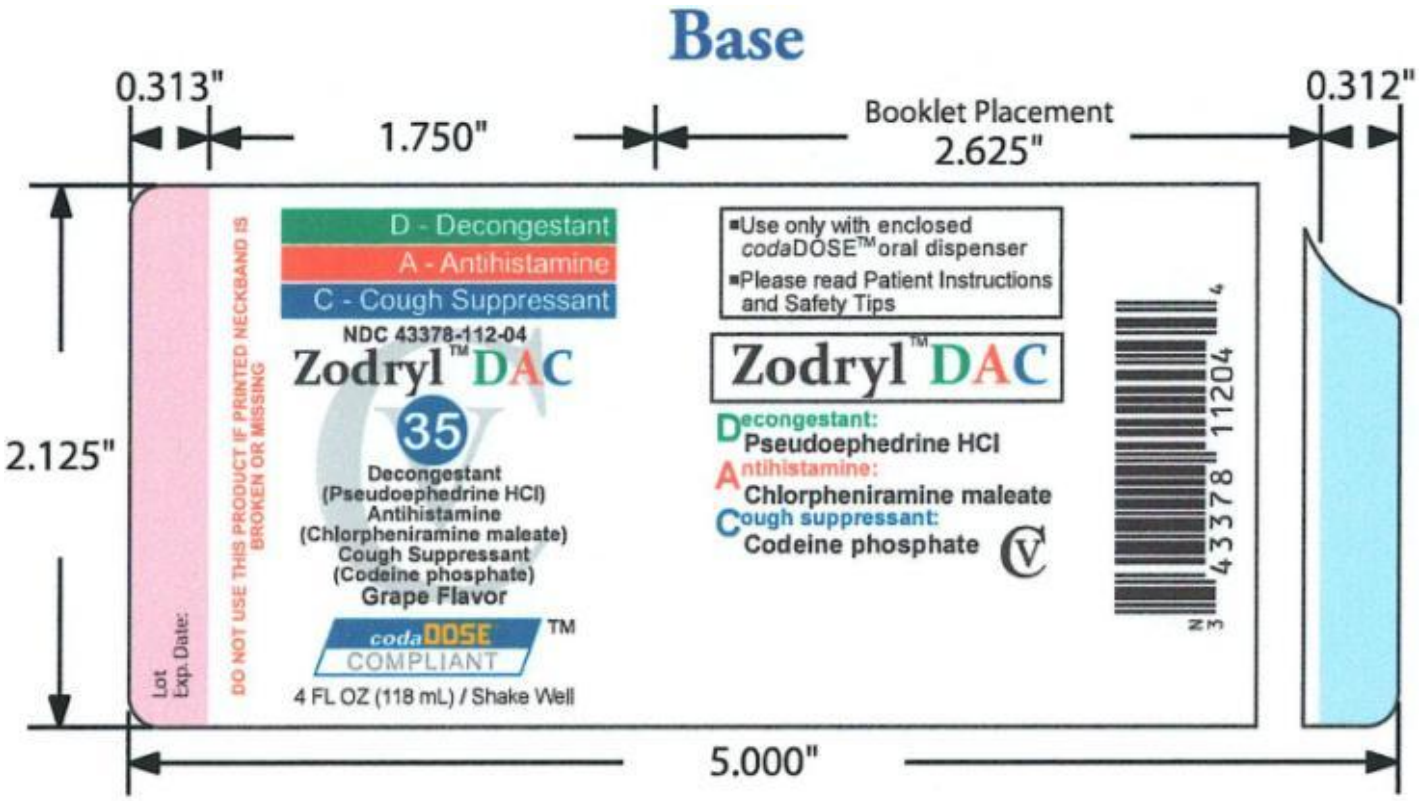


**Figure 1. Primary Label- Front Page**

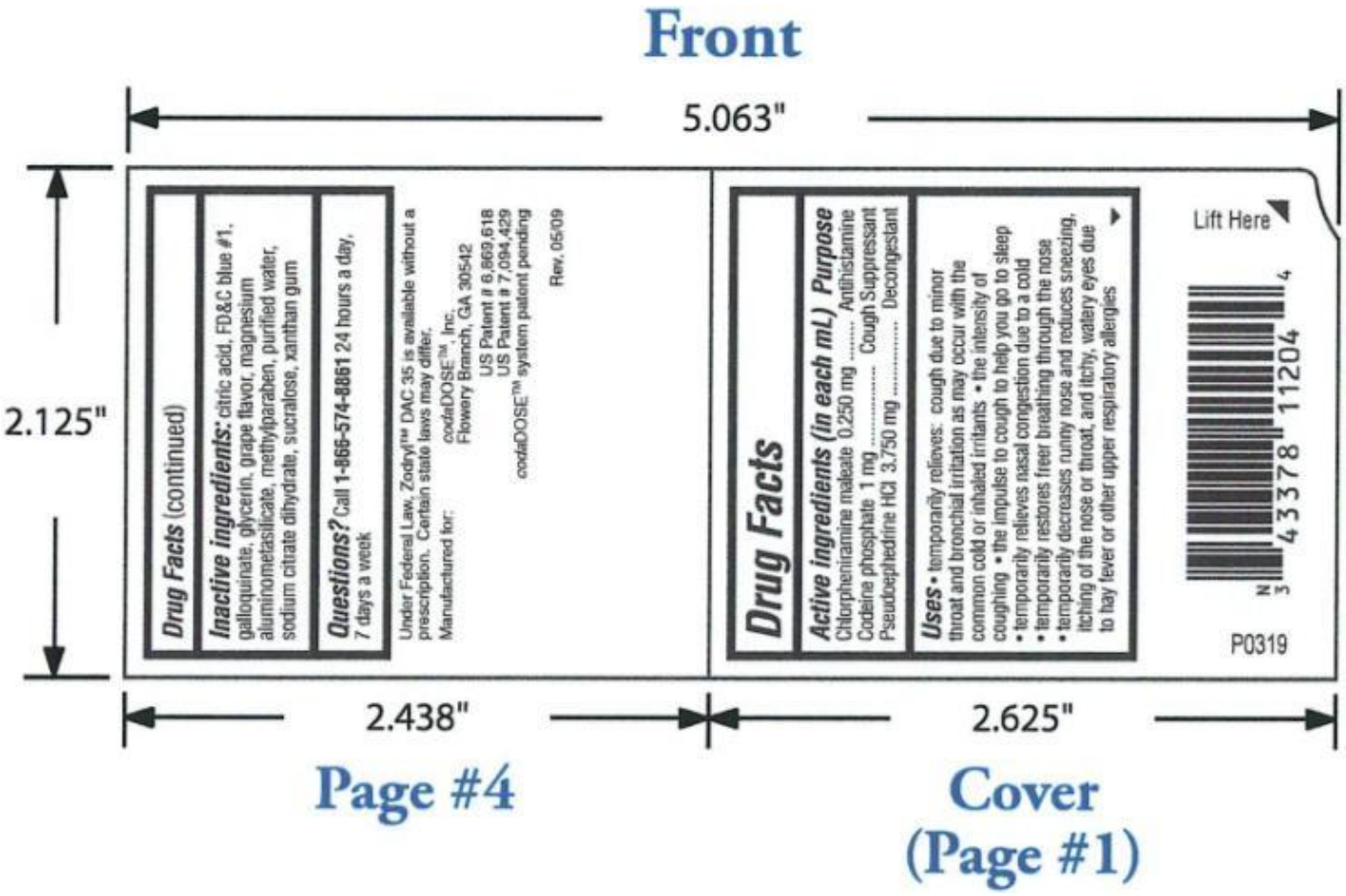


**Figure 2. Primary Label – Second Page**

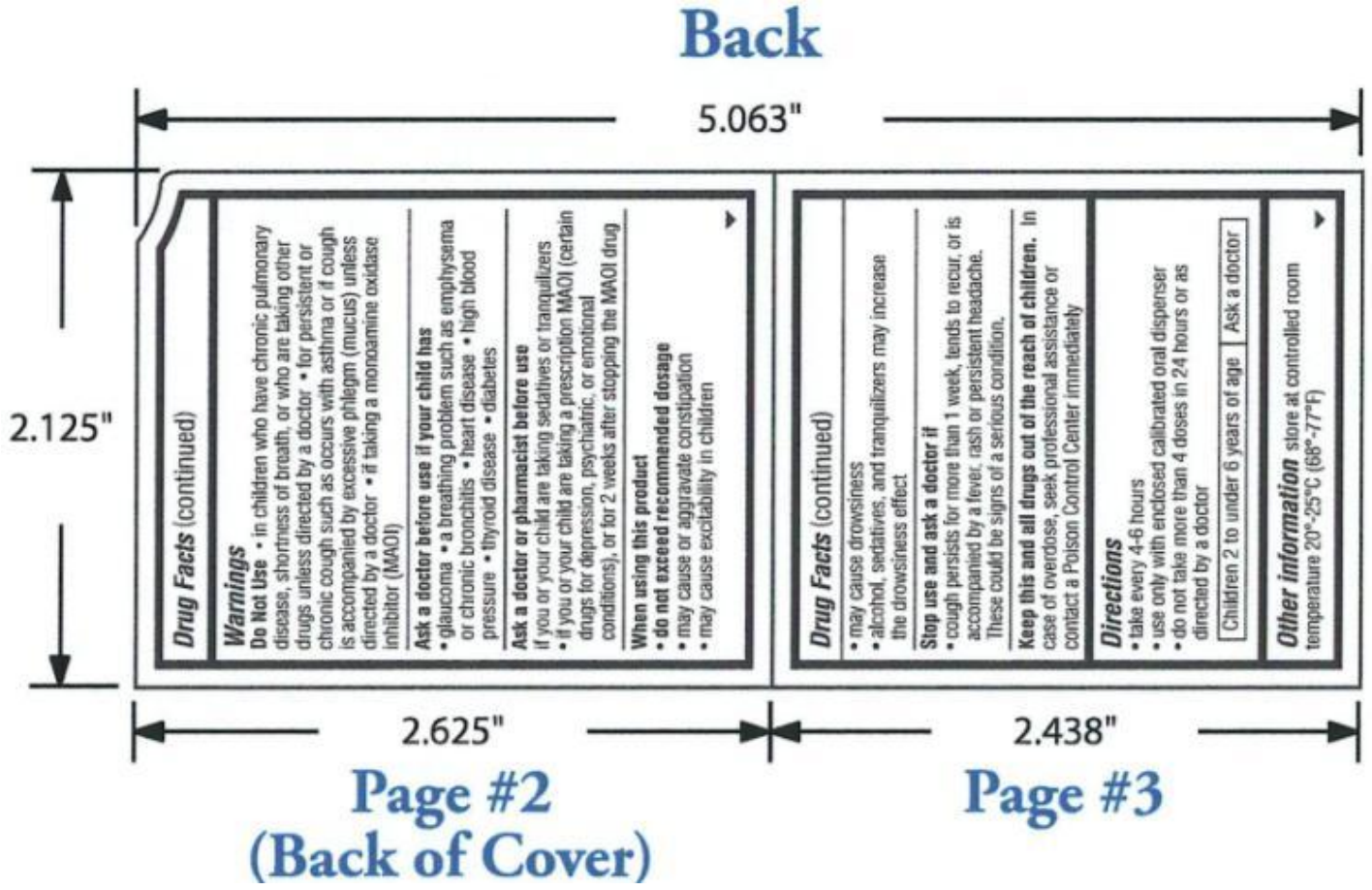

**Figure 3. Primary Label – Last Page**

# ZODRYL DAC 35

chlorpheniramine maleate,codeine phosphate and pseudoephedrine hydrochloride suspension

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:43378-112 |
| **Route of Administration** | ORAL | **DEA Schedule** | CV |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **CHLORPHENIRAMINE MALEATE** (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U) | CHLORPHENIRAMINE MALEATE | 1 mg in 4 mL |
| **CODEINE PHOSPHATE** (UNII: GSL05Y1MN6) (CODEINE - UNII:Q830PW7520) | CODEINE PHOSPHATE | 4 mg in 4 mL |
| **PSEUDOEPHEDRINE HYDROCHLORIDE** (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F) | PSEUDOEPHEDRINE HYDROCHLORIDE | 15 mg in 4 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **TANNIC ACID** (UNII: 28F9E0DJY6) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **MAGNESIUM ALUMINUM SILICATE** (UNII: 6M3P64V0NC) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM CITRATE** (UNII: 1Q73Q2JULR) | |
| **SUCRALOSE** (UNII: 96K6UQ3ZD4) | |
| **XANTHAN GUM** (UNII: TTV12P4NEE) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | blue | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | GRAPE | **Imprint Code** | |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:43378-112-04 | 118 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. | | 791919678 | manufacture |

Revised: 9/2009 CodaDose Inc.