**COLD AND FLU NIGHT TIME MULTI-SYMPTOM RELIEF ORIGINAL-**
**acetaminophen, dextromethorphan hbr, doxylamine succinate liquid**
**Pharmacy Value Alliance, LLC**

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**Cold & Flu Night-time Multi-Symptom Relief**

***DRUG FACTS***

**Active ingredients (in each 30 mL dose cup)**

| | |
|---|---|
| Acetaminophen | 650 mg |
| Dextromethorphan HBr | 30mg |
| Doxylamine Succinate | 12.5 mg |

***Purpose***

| | |
|---|---|
| Acetaminophen | Pain reliever/fever reducer |
| Dextromethorphan HBr | Cough suppressant |
| Doxylamine Succinate | Antihistamine |

***Uses*** temporarily relieves cold/flu symptoms: • sore throat • headache
• minor aches and pain • fever • runny nose and sneezing
• cough due to minor throat and bronchial irritation

***Warnings***

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take
• more than 4,000 mg of Acetaminophen in 24 hours, which is the maximum daily amount
• with other drugs containing acetaminophen
• 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 askin reaction occurs, stop use and seek medical help right away.

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

**Do not use** • with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
• 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.
• to make a child sleepy

**Ask a doctor before use if you have**
• a sodium restricted diet • liver disease • 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

• trouble urinating due to enlarged prostate gland.

**Ask a doctor or pharmacist before use**
• if you are taking sedatives or tranquilizers
• if you are taking the blood thinning drug warfarin

**When using this product** • do not use more than directed
• avoid alcoholic drinks • excitability may occur, especially in children
• marked drowsiness may occur
• be careful when driving a motor vehicle or operating machinery
• alcohol, sedatives, and tranquilizers may increase drowsiness

**Stop use and ask a doctor if** • redness or swelling is present
• symptoms do not get better within 7 days or are accompanied by a fever
• fever gets worse or lasts more than 3 days • new symptoms occur
• cough lasts more than 7 days, 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.**

Overdose warning: Taking more than the recommended dose can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions** • take only as recommended-see Overdose warning
• Use dose cup or tablespoon (TBSP)
• do not exceed 4 doses per 24 hours

| | |
|---|---|
| adults and children 12 years and over | 30 mL (2 TBSP) every 6 hours |
| children 4 to under 12 years | ask a doctor |
| children under 4years | do not use |

• If taking Night Time at night and Day Time during the day, limit total to 4 doses per 24 hours.

***Other information*** • each 30 mL dose cup contains: sodium 45 mg • store at room temperature

**Inactive ingredients** citric acid, D&C yellow # 10, FD&C Green No.3, FD&C Yellow No.6, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose

**QuestIons?** Call weekdays from 9:30 am to 4:30 pm EST. **1-877-798-5944.**

**Principal Display Panel**

**Premier® Value**

**COMPARE TO THE ACTIVE**

**INGREDIENTS IN**

**VICKS® NYQUIL®***

**Original Flavor**

**COLD & FLU**
**Night-time Multi-Symptom Relief**

Acetaminophen..... Pain Reliever/Fever Reducer
Dextromethorphan Hbr..... Cough Suppressant
Doxylamine Succinate.....Antihistamine

**Non-drowsy**

8 FL OZ (237 mL)

**INDEPENDENTLY TESTED**
**PV**
**SATISFACTION GUARANTEED**

**DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN**
**Failure to follow these warnings could result in serious consequences**

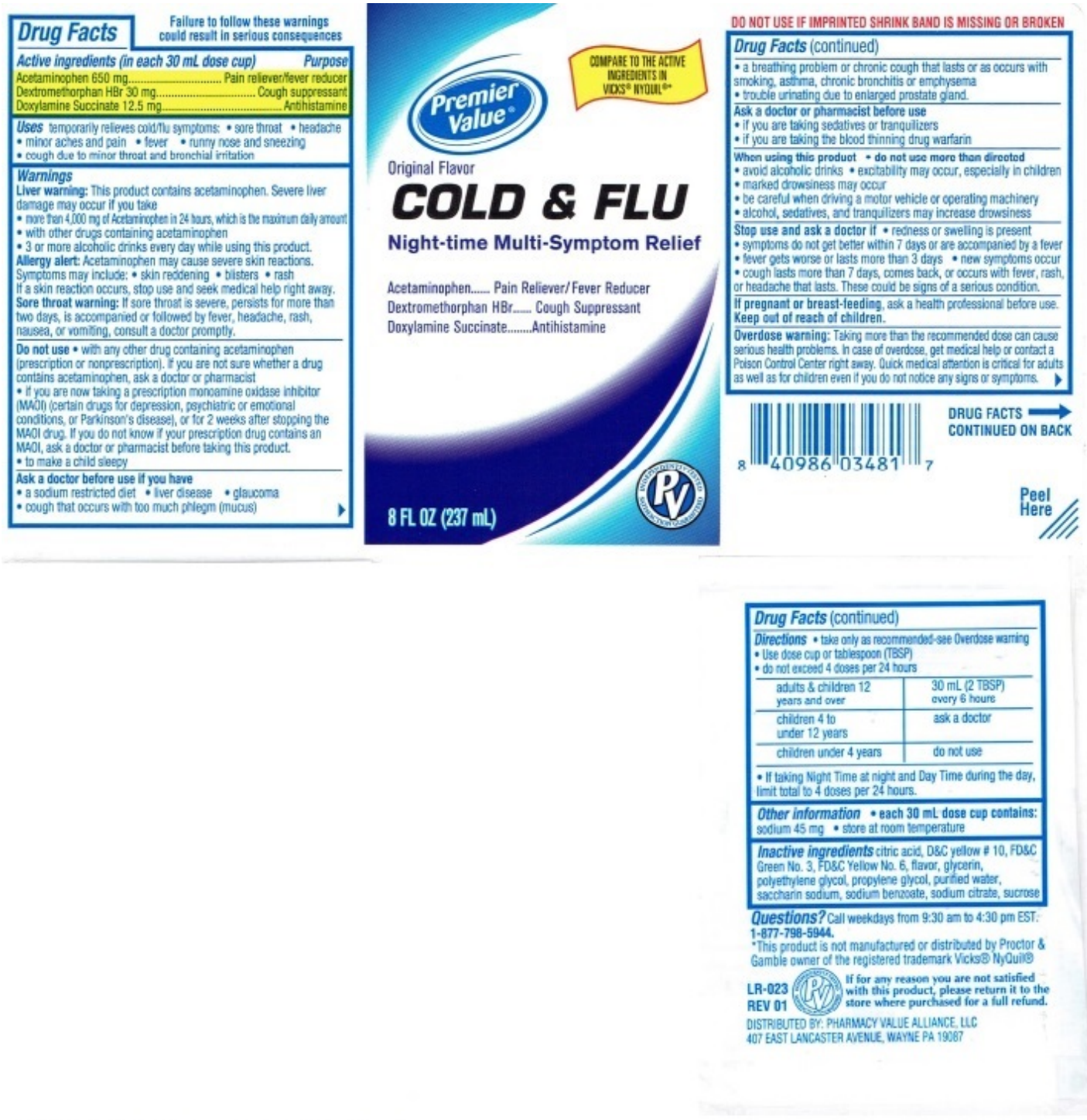
**Questions?** Call weekdays **1-877-798-5944.**
*This product is not manufactured or distributed by Proctor & Gamble, owner of the registered trademark Vicks® NyQuil®.
If for any reason you are not satisfied with this product, please return It to the store where purchased for a full refund.

DISTRIBUTED BY: PHARMACY VALUE ALLIANCE, LLC
407 EAST LANCASTER AVENUE, WAYNE PA 19087

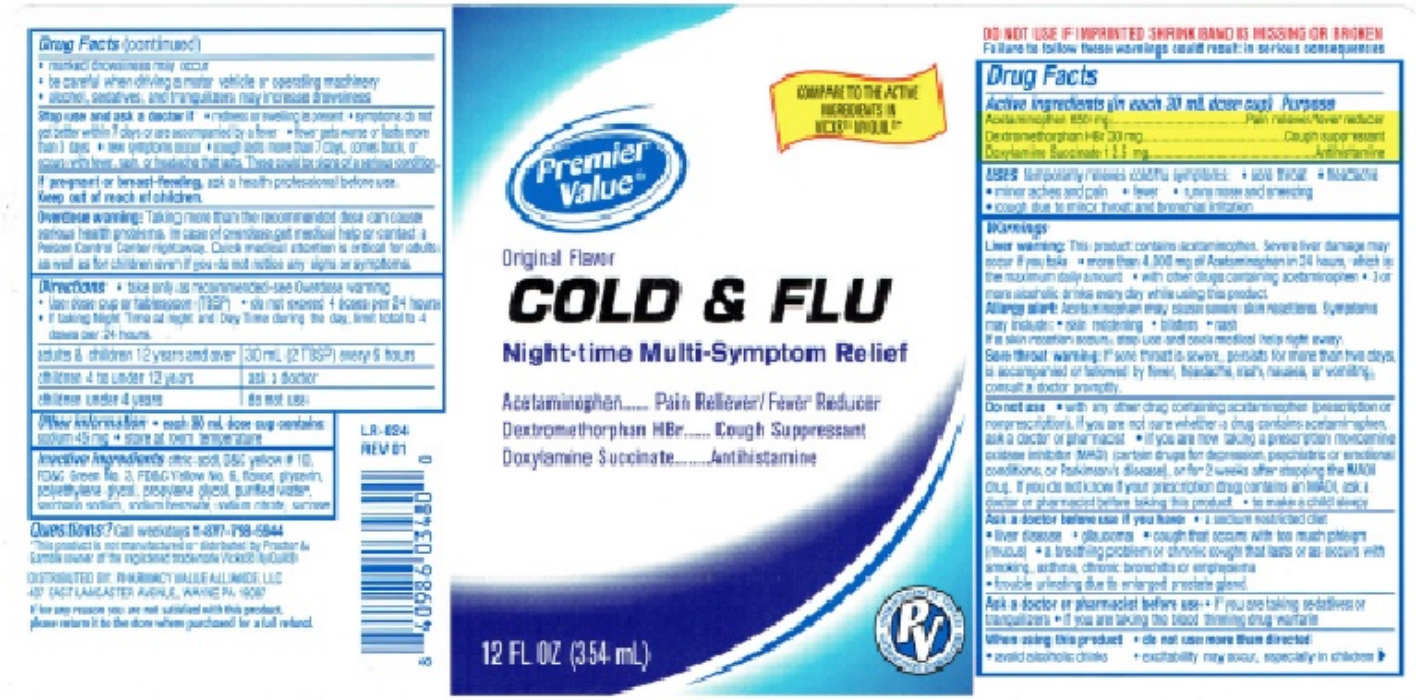
LR-023

REV-01

Product label - 8 OZ Package




Product label - 12 OZ Package




Premier® Value Cold & Flu Night-time Multi-Symptom Relief Original

# COLD AND FLU NIGHT TIME MULTI-SYMPTOM RELIEF ORIGINAL

acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:68016-239 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 650 mg in 30 mL |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 30 mg in 30 mL |
| **DOXYLAMINE SUCCINATE** (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) | DOXYLAMINE SUCCINATE | 12.5 mg in 30 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL) | |
| **D&C YELLOW NO. 10** (UNII: 35SW5USQ3G) | |
| **FD&C GREEN NO. 3** (UNII: 3P3ONR6O1S) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |

| | |
|---|---|
| **WATER** (UNII: 059QF0KO0R) | |
| **SACCHARIN SODIUM** (UNII: SB8ZUX40TY) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **SODIUM CITRATE** (UNII: 1Q73Q2JULR) | |
| **SUCROSE** (UNII: C151H8M554) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:68016-239-08 | 237 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/01/2018 | |
| **2** | NDC:68016-239-12 | 354 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/01/2018 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M012 | 10/01/2018 | |

## Labeler - Pharmacy Value Alliance, LLC (101668460)

## Registrant - AptaPharma Inc. (790523323)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| AptaPharma Inc. | | 790523323 | manufacture(68016-239) |

Revised: 12/2023 Pharmacy Value Alliance, LLC