**FAMILY CARE COLD AND FLU NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate liquid**
**United Exchange Corp.**

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

Acetaminophen 650 mg.....Pain reliever/fever reducer

Dextromethorphan HBr 30 mg.....Cough suppressant

Doxylamine succinate 12.5 mg.....Antihistamine

Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- running nose and sneezing

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4 doses in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Sore throat warning: if sore throat is severe, lasts for more than 2 days, occurs with or is 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 MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or occurs with smoking, asthma, chronic bronchitis or emphysema
- trouble urinating due to enlarged prostate gland
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- pain or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occurs
- cough comes back, or occurs with 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 our of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

Directions

- take only as directed
- use dose cup or tablespoon (TBSP)
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over: 30 mL (2 TBSP) every 6 hrs

children 4 to under 12 yrs: ask a doctor

children under 4 yrs: do not use

Other information

- each 30 mL dose cup contains: potassium 4 mg
- sodium 33 mg
- store at room temperature

Inactive ingredietns

acesulfame potassium, alcohol, citric acid hydrate, FD&C Green No. 3, FD&C No. 5, glycerin, high fructose corn syrup, L-menthol, methylparaben, mint essence, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium citrate hydrate, sodium chloride, sodium saccharin

Distributed by:

United Exchange Corp.

Cerritos, CA 90703 U.S.A.

Made in Korea


# FAMILY CARE COLD AND FLU NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate liquid

## Product Information

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|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:65923-629 |
| **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 |
|---|---|
| **ACESULFAME POTASSIUM** (UNII: 23OV73Q5G9) | |
| **ALCOHOL** (UNII: 3K9958V90M) | |
| **HYDROXYCITRIC ACID** (UNII: 8W94T9026R) | |

| | |
|---|---|
| **FD&C GREEN NO. 3** (UNII: 3P3ONR6O1S) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **HIGH FRUCTOSE CORN SYRUP** (UNII: XY6UN3QB6S) | |
| **MENTHOL** (UNII: L7T10EIP3A) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **POLYETHYLENE GLYCOLS** (UNII: 3WJQ0SDW1A) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM CHLORIDE** (UNII: 451W47IQ8X) | |
| **SACCHARIN SODIUM** (UNII: SB8ZUX40TY) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:65923-629-04 | 118 mL in 1 BOTTLE, PLASTIC; 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 | 07/21/2015 | |

## Labeler - United Exchange Corp. (840130579)

Revised: 7/2015 United Exchange Corp.