

**NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hbr,
doxylamine succinate liquid
Kroger**

782L-Kroger-Nighttime Cold & Flu Multi-Symptom Relief-12oz

Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Uses temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny 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 every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 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.

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 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
- 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 occur
- 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 out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 directed
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over-30 mL every 6 hrs

children 4 to under 12 yrs-ask a doctor

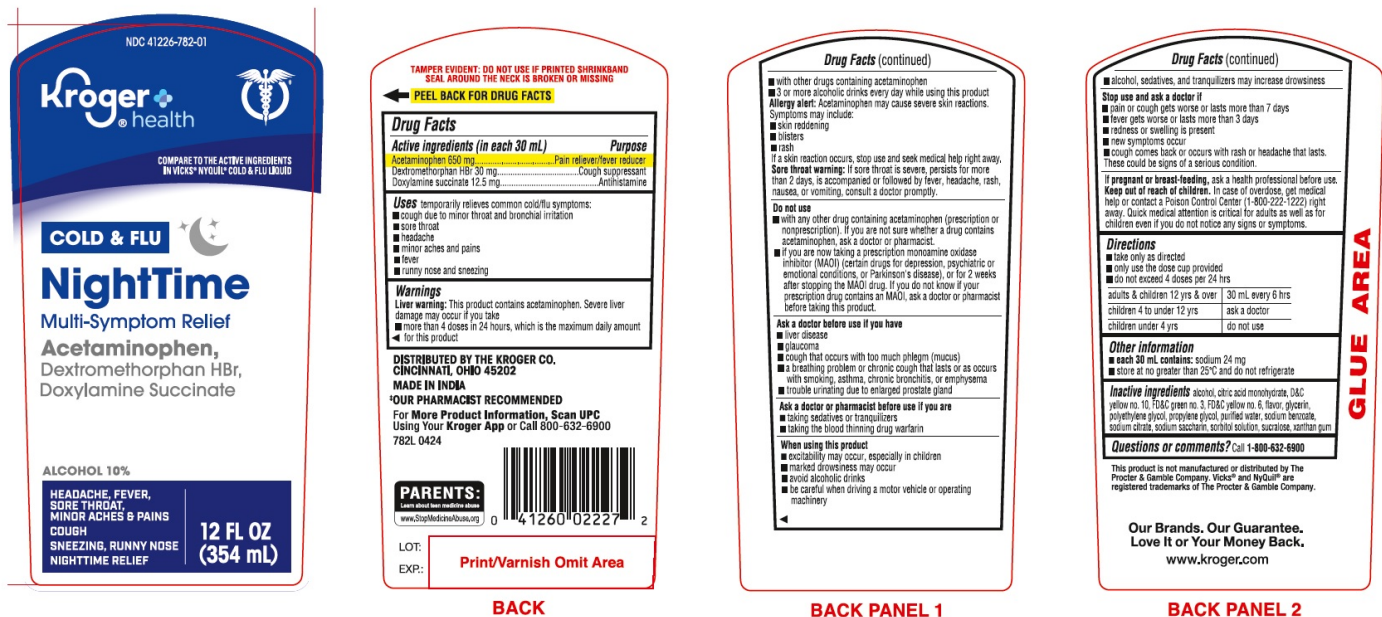
children under 4 yrs-do not use

Other information

- each 30 mL contains: sodium 24 mg
- store at no greater than 25°C and do not refrigerate

Inactive ingredients alcohol, citric acid monohydrate, D&C yellow no. 10, FD&C green no. 3, FD&C yellow no. 6, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol solution, sucralose, xanthan gum

Questions or comments? Call **1-800-632-6900**



| NIGHTTIME COLD AND FLU | | | |
|--|----------------|-------------------------------|------------------|
| acetaminophen, dextromethorphan hbr, doxylamine succinate liquid | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41226-782 |
| Route of Administration | ORAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL) | | DOXYLAMINE SUCCINATE | 12.5 mg in 30 mL |
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | | ACETAMINOPHEN | 650 mg in 30 mL |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | | DEXTROMETHORPHAN HYDROBROMIDE | 30 mg in 30 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALCOHOL (UNII: 3K9958V90M) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| SORBITOL SOLUTION (UNII: 8KW3E207O2) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| WATER (UNII: 059QF0K00R) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |

Product Characteristics

| | | | |
|----------|---------------------------|--------------|--|
| Color | green (Clear green color) | Score | |
| Shape | | Size | |
| Flavor | ANISE | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:41226-782-01 | 354 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/30/2024 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M012 | 04/30/2024 | |

Labeler - Kroger (006999528)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| MARKSANS PHARMA LIMITED | | 677604129 | manufacture(41226-782) |

