**NITETIME COUGH- nitetime cough liquid**
**KINGSTON PHARMA LLC**

*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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## NITETIME COUGH

Active Ingredient (in each 15 mL = 1 tablespoon):
Acetaminophen 325 mg
Dextromethorphan HBr 15 mg
Doxylamine Succinate 6.25 mg

Purpose:
Pain reliever/fever reducer
Cough suppressant
Antihistamine

### *Uses*

- Temporarily relieves these common cold/flu symptoms
  1. Cough due to minor throat and bronchial irritation
  2. Runny nose and sneezing
  3. Minor aches and pains
  4. Headache
  5. Sore throat
  6. Fever

### *Warnings*

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if adult/child takes

- More than 4 doses in 24 hours, which is the maximum daily amount for this product.
- With other drugs containing acetaminophen.
- Adult has 3 or more alcoholic drinks every day while using this product.

**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.
- To make a child sleep.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL ON THE BOTTLE IS BROKEN OR MISSING.

**Ask a doctor before use if you have**

- Glaucoma
- Liver disease
- Heart disease
- High blood pressure

- Thyroid disease
- Diabetes
- Trouble urinating due to an enlarged prostate gland
- Persistent or chronic cough such as occurs with smoking, asthma or emphysema
- Cough that occurs with too much phlegm (mucus)
- 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**
- **Do not exceed recommended dosage**
- Excitability may occur especially in children
- Marked drowsiness may occur
- Avoid alcoholic drinks
- Alcohol, sedatives and tranquilizers may increase drowsiness
- Be careful when driving a motor vehicle or operating machinery

**Stop use and ask doctor if**
- 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

**Keep this and all drugs out of the reach of children.** In case of accidental overdose, seek professional assistance or contact a Poison control center right away.

**If pregnant or breast-feeding,** ask a health professional before use.

***Directions:***
- Do not take more than directed.
- Use enclosed dosing cup.
- Do not take more than 4 doses in 24-hours.
- **Adults and children 12 years and over:** take 2 tablespoons (TBSP) or 30 mL every 6 hours.
- **Children 4 to under 12 years:** ask a doctor
- **Children under 4 years:** do not use
- **When using other Daytime or Nite time products, carefully read each label to insure correct dosing**

***Other information***
- Store between 15-30 degree Celsius (59-86 degree Fahrenheit)
- Each tablespoon contains: Sodium 46mg

***Inactive ingredients:*** Alcohol, Anhydrous citric acid, FD&C blue 1, FD&C red 40, flavor, High fructose corn syrup, Polyethylene glycol, Propylene glycol, Saccharin sodium, Sodium citrate and Purified Water.

**(packs: 4oz, 6oz, 10oz & 12oz) Kingston NDC# 71027-041-06**

**Manufactured by: Kingston Pharma LLC**
**5 County Route 42**
**Massena, NY 13662**



# NITETIME COUGH

nitetime cough liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:71027-041 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg in 15 mL |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 15 mg in 15 mL |
| **DOXYLAMINE SUCCINATE** (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) | DOXYLAMINE SUCCINATE | 6.25 mg in 15 mL |

**Inactive Ingredients**

| Ingredient Name | Strength |
|---|---|
| **ALCOHOL** (UNII: 3K9958V90M) | |
| **ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **METHYL SALICYLATE** (UNII: LAV5U5022Y) | |
| **HIGH FRUCTOSE CORN SYRUP** (UNII: XY6UN3QB6S) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WJQ0SDW1A) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **SACCHARIN SODIUM** (UNII: SB8ZUX40TY) | |
| **SODIUM CITRATE, UNSPECIFIED FORM** (UNII: 1Q73Q2JULR) | |
| **WATER** (UNII: 059QF0KO0R) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:71027-041-06 | 1 in 1 CARTON | 03/01/2017 | |
| **1** | | 177 mL in 1 BOTTLE; 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 | 03/01/2017 | |

## Labeler - KINGSTON PHARMA LLC (080386521)

## Registrant - KINGSTON PHARMA LLC (080386521)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| KINGSTON PHARMA LLC | | 080386521 | manufacture(71027-041) |

Revised: 1/2019 KINGSTON PHARMA LLC