

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.

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**



NIGHT TIME COLD & FLU
COMPARE TO ACTIVE
INGREDIENTS IN
Vicks® NyQuil®*

Pain Reliever, Fever Reducer
Cough Suppressant, Antihistamine

Multi-Symptom Relief

This product is not manufactured or distributed by
Procter & Gamble, distributor of Vicks® NyQuil®.

4 FL OZ (120 mL) Liquid

*TEMPER EVIDENT: DO NOT USE THIS PRODUCT IF
PRINTED INNER CAP SEAL IS BROKEN OR MISSING

Drug Facts

Active ingredients (in each 15 mL) Purpose
Acetaminophen 325 mg Pain reliever/fever reducer
Dextromethorphan HBr 15 mg Cough suppressant
Doxylamine succinate 6.25 mg Nasal decongestant

Uses ■ temporarily relieves these common cold/flu symptoms
■ minor aches and pains ■ headache ■ sore throat ■ runny nose and
sneezing ■ fever ■ cough due to minor throat and bronchial irritation

Warnings
Liver warning: This product contains acetaminophen. The maximum daily dose
of this product is 4 doses. Severe liver damage may occur if adult/daily takes
■ more than 4,000 mg of acetaminophen in 24 hours
■ with other drugs containing acetaminophen.
■ 3 or more alcoholic drinks every day while using this product.
Some 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.
■ if you have ever had an allergic reaction to this product or any of its ingredients.
■ to make child sleepy

PEEL HERE

Drug Facts (continued)

ask a doctor before use if you have ■ liver disease ■ glaucoma
■ a sodium restricted diet ■ trouble urinating due to an enlarged
prostate gland ■ 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

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

When using this product ■ do not use more than directed
■ 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 doctor if ■ redness or swelling is present
■ pain or cough gets worse or lasts more than 7 days ■ fever gets
worse or lasts more than 3 days ■ 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

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. Prompt 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. (see overdose warning)
■ use dose cap. ■ do not use more than 4 doses in 24-hours.
adults and children 12 years and over 32ml every 6 hours
children 4 to 12 years ask a doctor
children under 4 years do not use

■ when using other Day time or Night time products, carefully read
each label to insure correct dosing

Other information
■ Each 15 mL (tablespoon) dose contains: Sodium 46 mg
■ store at 15°-30°C (59°-86°F) ■ protect from freezing

Inactive ingredients alcohol, Citric acid, D&C yellow
no. 10, FD&C Green no. 3, FD&C yellow no. 6, flavor, high fructose corn
syrup, polyethylene glycol, propylene glycol, purified water, saccharin
sodium, sodium citrate, sodium benzoate.

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