DAYTIME COUGH- daytime 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.

Daytime Cough

Active Ingredient (in each 15 mL = 1 tablespoon):
Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

Purpose: Pain reliever/fever reducer
Cough suppressant
Nasal decongestant

Uses

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

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.
- If you have ever had an allergic reaction to this product or any of its ingredients.

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

Ask a doctor before use if you have

- 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 the blood thinning drug warfarin

When using this product
- **Do not exceed recommended dosage** (see overdose warning)

Stop use and ask doctor if
- Nervousness, dizziness or sleeplessness occur
- Symptoms get worse or last more than 5 days (children) or 7 days (adults)
- 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

Keep this and all drugs out of the reach of children.
Overdose Warning: In case of accidental overdose, seek professional assistance or contact a Poison control center right away. Quick medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

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

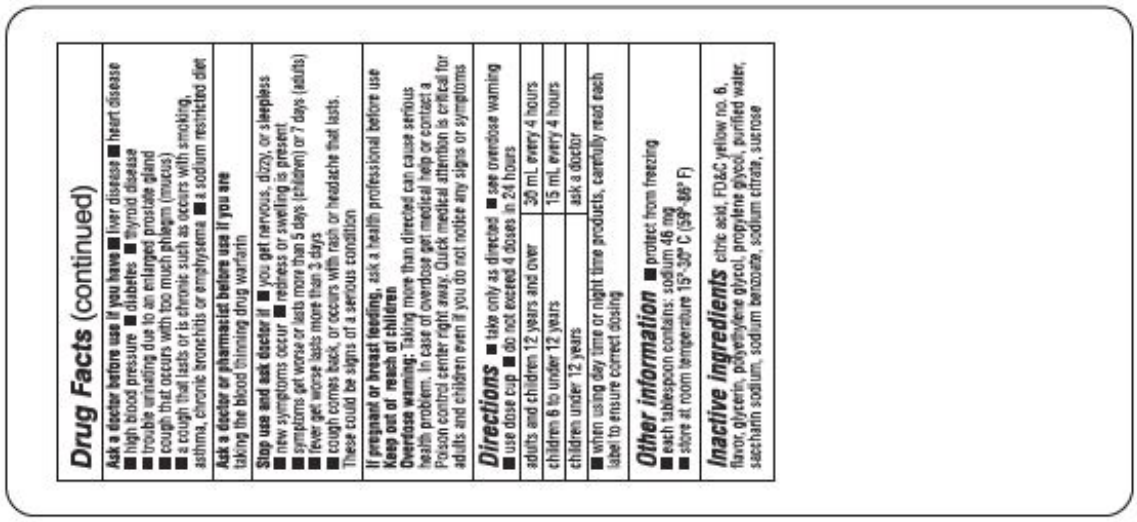
Directions:
- Do not take more than directed. (see overdose warning)
- Use enclosed dosing cup.
- Do not take more than 4 doses in 24-hours.
- **Adults and children 12 years and over:** take 2 tablespoons (TBSP) or 30 mL every 4 hours.
- **Children 6 to under 12 years:** take 1 tablespoon (TBSP) or 15 mL every 4 hours.
- **Children 4 to under 6 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 20-25 degree Celsius (68-77 degree Fahrenheit)
- Each tablespoon contains: Sodium 50mg

Inactive ingredients: Butylated hydroxyanisole, Edetate disodium, FD&C yellow 6, flavor, Glycerin, Menthol, Monobasic sodium phosphate, Polyethylene glycol, Propylene glycol, Saccharin sodium, Sucrose, Xanthan gum and Purified Water.

(packs: 4oz) Kingston NDC# 71027-040-06

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



Drug Facts (continued)

Ask a doctor before use if you have ■ liver disease ■ heart disease ■ high blood pressure ■ diabetes ■ thyroid disease ■ trouble urinating due to an enlarged prostate gland ■ cough that occurs with too much phlegm (mucus) ■ a cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema ■ a sodium restricted diet

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

Stop use and ask doctor if ■ you get nervous, dizzy, or sleepless ■ new symptoms occur ■ redness or swelling is present ■ symptoms get worse or lasts more than 5 days (children) or 7 days (adults) ■ fever get worse lasts more than 3 days ■ 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 directed can cause serious health problem. In case of overdose get medical help or contact a Poison control center right away. Quick medical attention is critical for adults and children even if you do not notice any signs or symptoms

Directions ■ take only as directed ■ see overdose warning ■ use dose cup ■ do not exceed 4 doses in 24 hours

adults and children 12 years and over	30 mL every 4 hours
children 6 to under 12 years	15 mL every 4 hours
children under 12 years	ask a doctor

■ when using day time or night time products, carefully read each label to ensure correct dosing

Other information ■ protect from freezing ■ each tablespoon contains: sodium 46 mg ■ store at room temperature 15°-30° C (59°-86° F)

Inactive ingredients citric acid, FD&C yellow no. 6, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose

DAYTIME COUGH

daytime cough liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71027-040
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	10 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71027-040-06	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(71027-040)

Revised: 1/2019 KINGSTON PHARMA LLC