CHILDRENS COUGH AND COLD- childrens cough and cold 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.

Children's Cough & Cold Liquid

Active Ingredient: Brompheniramine maleate 1 mg, Dextromethorphan HBr 5mg, Phenylephrine HCl 2.5 mg (in each 5 mL)

Purpose: Children's Cough & Cold

Cough & Cold

Warnings:

Do not use:

- 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.

Ask a doctor before use if you have

- Glaucoma
- Thyroid disease
- High blood pressure
- Heart 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 breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are

- Taking sedatives or tranquilizers

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

- Nervousness, dizziness or sleeplessness occur
- Symptoms do not get better within 7 days or are accompanied by fever
- Cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts

A persistent cough may be a sign 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.

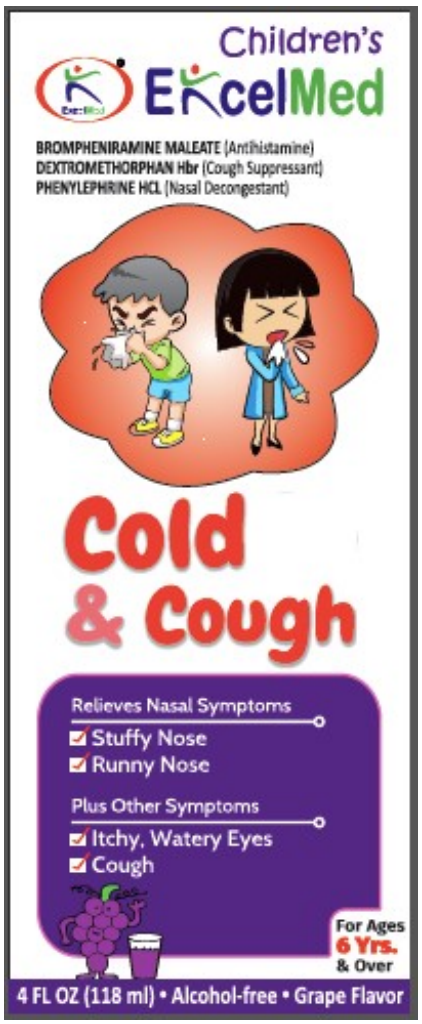
Directions:

- Use enclosed dosing cup.
- Do not take more than 6 doses in any 24-hour period.
- **Adults and children 12 years and over:** take 4 teaspoons or 20 mL every 4-6 hours.
- **Children 6 to under 12 years:** take 2 teaspoons or 10 mL every 4-6 hours. ask a doctor
- **Children 4 to under 6 years:** do not use unless directed by a doctor
- **Children under 4 years:** do not use

Store between 20°C to 25°C (68° to 77° F)

anhydrous citric acid, artificial flavor, FD&C blue no. 1, FD&C red no. 40, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose

(packs: 4oz) Kingston NDC# 71027-047-04



CHILDRENS COUGH AND COLD

childrens cough and cold liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71027-047
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BROMPHENIRAMINE MALEATE (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	1 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71027-047-04	1 in 1 CARTON	03/01/2017	
1		118 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(71027-047)

Revised: 1/2019 KINGSTON PHARMA LLC