RAPID MAX MAXIMUM STRENGTH COOL AND CLEAR - COLD, FLU AND SORE THROAT- rapid max maximum strength cool and clear - cold, flu and sore throat 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.

ExcelMed Rapid Max Maximum Strength Cool & Clear- Cold, Flu & Sore throat

Active Ingredient: Each 20ml contains:
Acetaminophen 650 mg
Dextromethorphan 20 mg
Guaifenesin 400 mg
Phenylephrine 10 mg

Purpose:
Pain reliever, Fever Reducer
Cough Suppressant
Expectorant
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. helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

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

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

- for children under 12 years of age
- 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.
- 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 allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if you have

- diabetes
- liver disease
- heart disease
- thyroid disease
- high blood pressure
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to an enlarged prostate gland

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.

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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 Anhydrous Citric Acid, Disodium EDTA-Copper, Sodium Benzoate, Sucralose, Sodium Citrate, Propyl Gallate, Xanthan gum, Glycerin, Propylene glycol, Sorbitol, FD&C Blue#1, FD&C Red# 40 and Purified Water.

(packs: 6oz) Kingston NDC# 71027-019-06

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

RAPID MAX MAXIMUM STRENGTH COOL AND CLEAR - COLD, FLU AND SORE THROAT

rapid max maximum strength cool and clear - cold, flu and sore throat liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71027-019
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 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)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
SORBITOL (UNII: 506T60A25R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71027-019-06	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(71027-019)

Revised: 3/2017 KINGSTON PHARMA LLC