RAPID MAX MAXIMUM STRENGTH COOL AND CLEAR - COLD, SEVERE CONGESTION AND COUGH- rapid max maximum strength cool and clear - cold, severe congestion and 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.

ExcelMed Rapid Max Maximum Strength Cool & Clear- Cold, Severe Congestion & Cough

Active Ingredient: Each 20ml contains:
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. Cough due to minor throat and bronchial irritation

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

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

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, chronic bronchitis 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 20 mL every 4 hours.
- **Children under 12 years:** do not use

Other information

- Store between 20-25 degree Celsius (68-77 degree Fahrenheit)
- Each tablespoon contains: Sodium 13mg

Inactive ingredients citric acid, dextrose, flavors, glycerin, methyl paraben, potassium sorbate, propylene glycol, propyl paraben, purified water, red 33, red 40, saccharin sodium, sodium hydroxide, sucralose, xanthan gum

(packs: 6oz) Kingston NDC# 71027-020-06

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

RAPID MAX MAXIMUM STRENGTH COOL AND CLEAR - COLD, SEVERE CONGESTION AND COUGH

rapid max maximum strength cool and clear - cold, severe congestion and cough liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71027-020
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
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**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
GLYCERIN (UNII: PDC6A3C0OX)	

METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71027-020-06	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(71027-020)

Revised: 3/2017 KINGSTON PHARMA LLC