CHILDRENS TUSSIN DM- childrens tussin dm 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 Tussin DM

Active Ingredient: Active Ingredient: Dextromethorphan HBr 5mg, Guaifenesin 100mg (in each 5 mL)

Purpose:
Cough suppressant
Expectorant

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to coughs more productive

DO NOT USE IF PRINTED SEAL OVER IS TORN OR MISSING

Warnings:

Do not use if a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if the child has
- Cough that occurs with too much phlegm (mucus)
- Persistent or chronic cough such as occurs with asthma

Stop use and ask doctor if cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.

Keep this and all drugs out of the reach of children. In case of overdose, seek professional assistance or contact a Poison control center right away.

Directions:
- This product does not contain directions or complete warnings for adult use.
- Use only enclosed dosing cup provided.
- Do not take more than 6 doses in any 24-hour period.
- **Children 6 years to under 12 years:** 5 mL – 10 mL taken every 4 hours.
- **Children 4 years to under 6 years:** 2.5 mL – 5 mL taken every 4 hours.
- **Children under 4 years:** do not use.

Other information
- each teaspoon contains: sodium 4 mg
- store at 20°-25°C (68°-77°F)

Inactive ingredients
Anhydrous citric acid, Artificial & Natural flavors, FD&C Blue#1, FD&C red 40, Sucralose, Glycerin, Polyethylen Glycol, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Benzoate

(packs: 4oz) Kingston NDC# 71027-036-04

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

CHILDRENS TUSSIN DM

childrens tussin dm liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71027-032
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 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)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71027-032-04	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(71027-032)