

**G-TRON PEDIATRIC DROPS- dextromethorphan hbr, guaifenesin, phenylephrine hcl solution/
drops**

KRAMER NOVIS

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.

G-TRON PEDIATRIC DROPS

Active Ingredients

Dextromethorphan HBr, 5 mg

Guaifenesin, 100 mg

Phenylephrine HCL 2.5 mg

Purpose

Antitussive

Expectorant

Nasal Decongestant

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Uses

Non-narcotic cough suppressant which temporarily calms cough due to minor throat and bronchial irritation as may occur with the common cold • calms the cough control center and relieves coughing • helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive • temporarily relieves nasal congestion due to the common cold • helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure

Warnings

Tamper Evident Feature: Do not use if cap seal is torn, broken or missing.

Directions

Do not exceed 6 doses in any 24-hour period, or as directed by physician. Children 6 to under 12 years of age • 2 mL every 4 hours. Children 2 to under 6 years of age, ask a doctor.

Other information

- Tamper Evident Feature: Do not use if cap seal is torn, broken or missing.
- Store at controlled room temperature 15°-30°C (59°-86°F).
- Avoid excessive heat and humidity.

Citric acid, flavor, menthol, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, sorbitol solution and sucralose.

Manufactured in the USA for Kramer -Novis, San Juan, PR 00917.

Tel: (787)767-2072. www.kramernovis.com

* Broncotron® PED Drops is a registered trademark of Seyer Pharmatec.
This product is not manufactured, distributed or marketed by Seyer Pharmatec.

Packaging

NDC 52083-679-01	
G-TRON®	
PEDIATRIC DROPS	
Contains the same active ingredients as Broncotron® PED Drops*	
Antitussive • Expectorant Nasal Decongestant	
Sugar, Alcohol, Dye & Gluten Free	
SEE CARTON FOR FULL PRESCRIBING INFORMATION	
NET CONTENT: 30 mL (1 Fl. Oz.)	
	
Drug Facts	
Active Ingredients (in each 1 mL)	Purpose
Dextromethorphan HBr, 5 mg.....	Antitussive
Guaifenesin, 100 mg.....	Expectorant
Phenylephrine HCl, 2.5 mg.....	Nasal Decongestant
Uses	
Non-narcotic cough suppressant which temporarily calms cough due to minor throat and bronchial irritation as may occur with the common cold • calms the cough control center and relieves coughing • helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive • temporarily relieves nasal congestion due to the common cold • helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure	
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Other information	
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Inactive ingredients	
Citric acid, flavor, menthol, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, sorbitol solution and sucralose.	
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Lot # Exp. Date	NON-VARNISH AREA

G-TRON PEDIATRIC DROPS

dextromethorphan hbr, guaifenesin, phenylephrine hcl solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52083-679
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 1 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MENTHOL (UNII: L7T10EIP3A)	

METHYL PARABEN (UNII: A2I8C7H9T)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN SODIUM (UNII: 625NNB0G9N)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	grape	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-679-01	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	09/09/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/09/2014	

Labeler - KRAMER NO VIS (090158395)

Registrant - KRAMER NO VIS (090158395)