GENCONTUSS- chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride solution
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.

GENCONTUSS

Drug Facts

Active Ingredients (in each 5mL tsp)

Chlorpheniramine Maleate, 2 mg

Dextromethorphan HBr, 10 mg

Phenylephrine HCL, 5 mg

Purpose

Antihistamine

Cough Suppressant

Nasal Decongestant

Uses

• For the temporary relief of runny nose, sneezing, itching of the nose or throat and itchy watery eyes due to hay fever or other upper respiratory allergies.

• Temporarily relieves cough due to minor throat and bronchial irritation occurring with the common cold.

• Temporarily relieves nasal congestion and restores freer breathing through the nose.

Warnings

Do not use

• To sedate a child or to make a child sleepy.

• If you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional condition or Parkinson's disease) or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains a MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

• Heart disease • Thyroid disease • Glaucoma • High blood pressure • Diabetes • Trouble urinating due to enlargement of the prostate gland • Cough that occurs with too much phlegm (mucus) • Breathing problems or persistent or chronic cough that lasts such as occurs with smoking, asthma, chronic bronchitis or emphysema.

Ask a doctor or pharmacist: If you are taking sedatives or tranquilizers

When using this product

• DO NOT EXCEED RECOMMENDED DOSE.

• Marked drowsiness may occur • Excitability may occur, especially in children • Avoid alcoholic beverages • Alcohol, sedatives and tranquilizers may increase the drowsiness effect. Be careful when driving a motor vehicle or operating machinery.

Stop use and ask a doctor if

• Nervousness, dizziness, or sleeplessness occur. • Symptoms do not improve within 7 days or are accompanied by fever• Cough persists for 1 week, tends to recur or is accompanied by fever, rash or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a healthcare professional before use.

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

Directions

• Do not exceed 6 doses in a 24-hour period, unless directed by a doctor

Adults and children 12 years of age and older	2 teaspoonfuls (10 mL) every 4 hours
Children 6 to under 12 years of age	1 teaspoonful (5 mL) every 4 hours
Children under 6 years of age	Do not use

Other information

• Tamper evident feature: Do not use if inner seal is torn, broken or missing.

• Store at controlled room temperature 15-30□C(59-86□F).

• Avoid excessive heat or humidity.

Inactive Ingredients

Purified water, potassium sorbate, sodium benzoate, citric acid, propylene glycol, sodium citrate, sucrose, sucralose, cherry flavor, and FD&C red#40.

Contains the same active ingredients as Rycontuss®*

ANTIHISTAMINE

COUGH SUPPRESSANT

NASAL DECONGESTANT

Cherry Flavor

Manufactured in the USA for Kramer Novis, San Juan, PR 00917. Tel:(787) 767-2072 www.kramernovis.com

*Rycontuss® is a registered trademark of Okendpharma Inc. This product is not manufactured, distributed or marketed by Okendpharma Inc.

Packaging

GENCONTUSS

chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52083-650
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics			
Color	red (Clear Red)	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-650-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/08/2015	

Labeler - KRAMER NOVIS (090158395)

Registrant - KRAMER NOVIS (090158395)

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