G-P-TUSS DXP - dexbrompheniramine maleate, dextromethorphan hydrobromide and phenylephrine hydrochloride syrup
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.

Drug Facts

Active ingredients (in each 5mL tsp)	Purpose
Dexbrompheniramine Maleate, 2 mg	Antihistamine
Dextromethorphan Hydrobromide, 20 mg	Cough suppressant
Phenylephrine HCl, 10 mg	Nasal Decongestant

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - sneezing
  - itchy nose or throat
  - runny nose
  - itchy, watery eyes
  - nasal congestion
- temporarily controls cough due to minor throat and bronchial irritation associated with inhaled irritants
- temporarily restores freer breathing through nose

Warnings

Do not use

- in 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

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or occurs with smoking, asthma, chronic bronchitis or emphysema.

Ask a doctor or pharmacist before use if the child is taking sedatives or tranquilizers

When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children
- may cause marked drowsiness
- sedatives and tranquilizers may increase the drowsiness effect

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- new symptoms occur
- symptoms do not improve within 7 days or are accompanied by fever
- cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health 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 take more than 6 doses in any 24-hour period
- **EVERY 4 HOURS**
- Adults and Children 12 years of age and older: 5 mL (1 tsp)
- Children 6 to under 12 years of age: (2.5 mL (1/2 tsp)
- Children under 6 years of age: consult physician

Other information

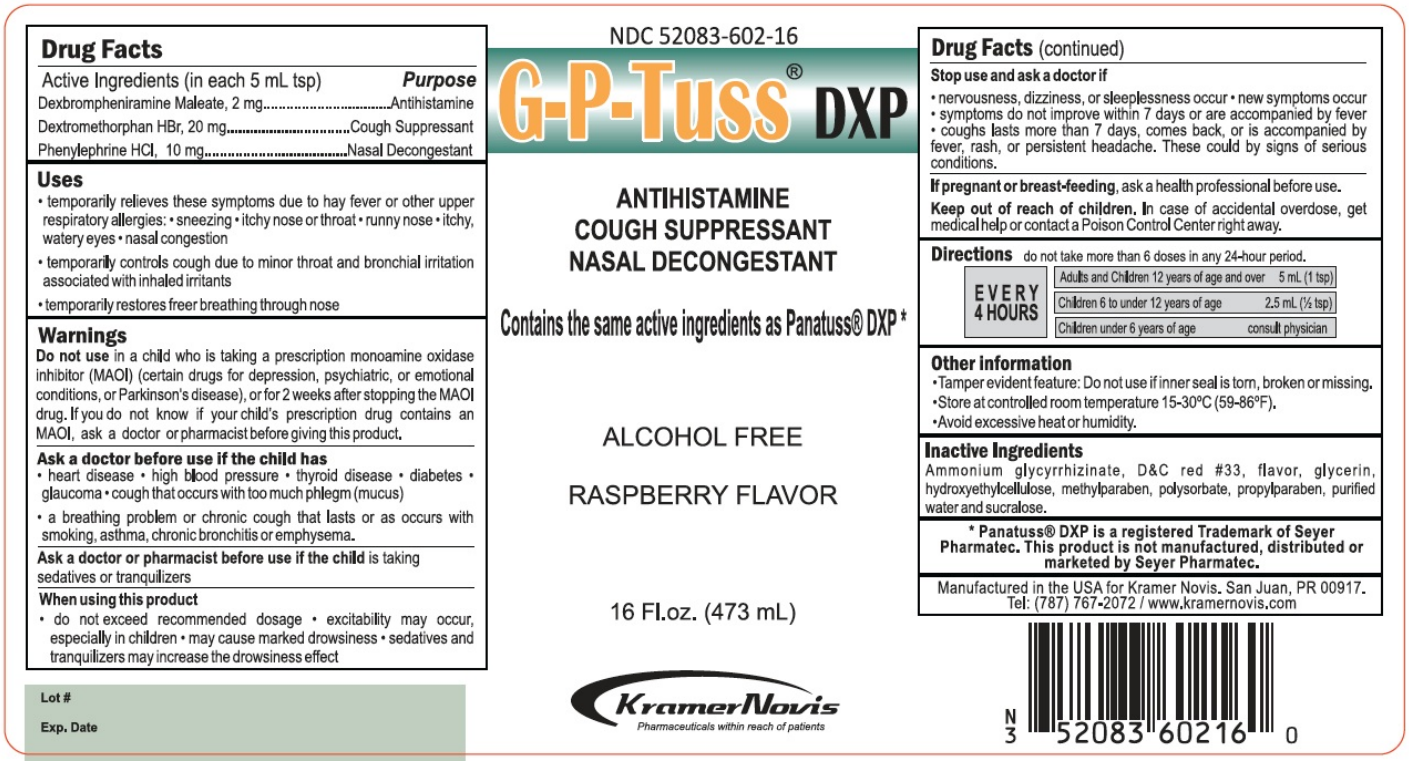
- Tamper evident feature: Do not use if inner seal is torn, broken or missing
- Store at controlled room temperature 15-30°C (59-86°F)
- Avoid excessive heat or humidity

Inactive ingredients

Ammonium glycyrrhizinate, D&C red #33, flavor, glycerin, hydroxyethylcellulose, methylparaben, polysorbate, propylparaben, purified water, and sucralose

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

PRINCIPAL DISPLAY PANEL - G-P-TUSS DXP



Drug Facts

Active Ingredients (in each 5 mL tsp) — **Purpose**

Dexbrompheniramine Maleate, 2 mg ..... Antihistamine

Dextromethorphan HBr, 20 mg ..... Cough Suppressant

Phenylephrine HCl, 10 mg ..... Nasal Decongestant

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • sneezing • itchy nose or throat • runny nose • itchy, watery eyes • nasal congestion
- temporarily controls cough due to minor throat and bronchial irritation associated with inhaled irritants
- temporarily restores freer breathing through nose

Warnings

Do not use in 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

- heart disease • high blood pressure • thyroid disease • diabetes • glaucoma • cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema.

Ask a doctor or pharmacist before use if the child is taking sedatives or tranquilizers

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- do not exceed recommended dosage • excitability may occur, especially in children • may cause marked drowsiness • sedatives and tranquilizers may increase the drowsiness effect

Lot #

Exp. Date

NDC 52083-602-16

G-P-Tuss® DXP

ANTIHISTAMINE
COUGH SUPPRESSANT
NASAL DECONGESTANT

Contains the same active ingredients as Panatuss® DXP *

ALCOHOL FREE

RASPBERRY FLAVOR

16 Fl.oz. (473 mL)

KramerNovis
Pharmaceuticals within reach of patients

Drug Facts (continued)

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur • new symptoms occur
- symptoms do not improve within 7 days or are accompanied by fever
- coughs lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could by signs of serious conditions.

If pregnant or breast-feeding, ask a health 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 take more than 6 doses in any 24-hour period.

EVERY 4 HOURS	
Adults and Children 12 years of age and over	5 mL (1 tsp)
Children 6 to under 12 years of age	2.5 mL (½ tsp)
Children under 6 years of age	consult physician

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

Ammonium glycyrrhizinate, D&C red #33, flavor, glycerin, hydroxyethylcellulose, methylparaben, polysorbate, propylparaben, purified water and sucralose.

*** Panatuss® DXP is a registered Trademark of Seyer Pharmatec. This product is not manufactured, distributed or marketed by Seyer Pharmatec.**

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

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NDC 52083-602-16

G-P-TUSS DXP

ANTIHISTAMINE
COUGH SUPPRESSANT
NASAL DECONGESTANT

ALCOHOL FREE
RASPBERRY FLAVOR

16 Fl. oz. (473 mL)
Kramer Novis

Pharmaceuticals within reach of patients

G-P-TUSS DXP

dexbrompheniramine, dextromethorphan, and phenylephrine syrup

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:52083-602
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXBROMPHENIRAMINE MALEATE (DEXBROMPHENIRAMINE)	DEXBROMPHENIRAMINE MALEATE	2 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (DEXTROMETHORPHAN)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (PHENYLEPHRINE)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
AMMONIUM GLYCYRRHIZATE	
D&C RED NO. 33	
GLYCERIN	
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%)	
METHYLPARABEN	
POLYSORBATE 20	
PROPYLPARABEN	
WATER	
SUCRALOSE	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	RASPBERRY (Raspberry Flavor)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-602-16	473 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/24/2013	

Labeler - Kramer Novis (090158395)

Revised: 1/2013

Kramer Novis