BRONTUSS DX- dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid
Portal Inc.

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.

Brontuss DX

Drug Facts

Active ingredients (in each 5 mL teaspoonful)	**Purpose**
Dextromethorphan Hydrobromide 20 mg.....	Antitussive
Guaifenesin 200 mg.....	Expectorant
Phenylephrine Hydrochloride 10 mg.....	Decongestant

Uses

temporarily relieves these symptoms, due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- nasal congestion
- reduces swelling of nasal passages

Warnings

Do not exceed recommended dosage.

Do not use this product

- 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

Ask a doctor before use if you have

- a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- a cough that occurs with too much phlegm (mucus)
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache. These could be signs of a serious condition.
- new symptoms occur

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.
In case of accidental overdose, seek professional help or contact a Poison Control Center immediately.

Directions
Do not exceed recommended dosage.

Adults and Children 12 years of age and older:	2 teaspoonfuls (10mL) every 6 hours, not to exceed 4 doses in a 24 hour period.
Children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 6 hours, not to exceed 4 doses in a 24 hour period.
Children under 6 years of age:	Not recommended for use.

Other information
Store at 59º-86ºF (15º-30ºC)

Inactive ingredients
cherry flavor, citric acid, maltitol, propylene glycol, purified water, sodium citrate, sodium saccharin, and sorbitol.

Questions? Comments?
Serious side effects associated with this product may be reported to this number.
Call (787)832-6645
Operation Hours: Monday - Friday, 8 A.M. to 4 P.M. Atlantic Standard Time (AST)
portalpharmaceutical@gmail.com

Manufactured for:
Portal Pharmaceutical
Mayaguez, PR 00680

Rev. 10/09

PRODUCT PACKAGING:
The packaging below represents the labeling currently used:

Principal Display Panel and Side Panel for 118mL Label:

NDC 49963-913-04

Brontuss
DX

Antitussive / Expectorant
Decongestant

Each teaspoonful (5 mL) for oral administration contains:
Dextromethorphan HBr..... 20 mg
Guaifenesin.....200 mg
Phenylephrine HCl..... 10 mg

Dye Free - Sugar Free
Alcohol Free - Gluten Free

4 oz. (118 mL)

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

Supplied in a tight, light-resistant container with a child-resistant cap.

Manufactured for:
Portal Pharmaceutical
Mayaguez, PR 00680

Rev. 10/09

Principal Display Panel and Side Panel for 15 mL Label:

NDC 49963-913-15

Brontuss
DX

Antitussive / Expectorant
Decongestant

Each teaspoonful (5 mL) for oral administration contains:
Dextromethorphan HBr..... 20 mg
Guaifenesin..... 200 mg
Phenylephrine HCl..... 10 mg

Dye Free / Sugar Free
Alcohol Free / Gluten Free

15 mL (1/2 fl oz)

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.
Supplied in a tight, light-resistant container with a child-resistant cap.

Professional Sample:
Not For Sale

Manufactured for:
Portal Pharmaceutical
Mayaguez, PR 00680

Rev. 10/09

Drug Facts (continued)

- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- nasal congestion
- reduces swelling of nasal passages

Warnings

Do not exceed recommended dosage.

Do not use this product

- 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

Drug Facts (continued)

Ask a doctor before use if you have

- a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- a cough that occurs with too much phlegm (mucus)
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache. These could be signs of a serious condition.
- new symptoms occur

Drug Facts (continued)

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

Keep out of the reach of children.

In case of accidental overdose, seek professional help or contact a Poison Control Center immediately.

Directions

Do not exceed recommended dosage.

Adults and Children 12 years of age and older:	2 teaspoonfuls (10 mL) every 6 hours, not to exceed 4 doses in a 24 hour period.
Children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 6 hours, not to exceed 4 doses in a 24 hour period.

Drug Facts (continued)

Children under 6 years of age:	Not recommended for use.

Other information

Store at 59° - 86° F (15° - 30° C)

Inactive ingredients

cherry flavor, citric acid, maltitol, propylene glycol, purified water, sodium citrate, sodium saccharin, and sorbitol.

Questions? Comments?

Serious side effects associated with this product may be reported to this number.
Call (787) 832-6645
Operation Hours: Monday-Friday, 8 A.M. to 4 P.M. Atlantic Standard Time (AST)
portalpharmaceutical@gmail.com

Manufactured for:
Portal Pharmaceutical
Mayagüez, PR 00680

Rev. 10/09

N 3 49963 91304 1

Lot: P0???? Exp. Date: ??/????

NDC 49963-913-15

Brontuss DX

• Antitussive • Expectorant
• Decongestant

Each teaspoonful (5 mL) for oral administration contains:

Dextromethorphan HBr	20 mg
Guaifenesin	200 mg
Phenylephrine HCl	10 mg

Dye Free - Sugar Free
Alcohol Free - Gluten Free
15 mL (1/2 fl oz)

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

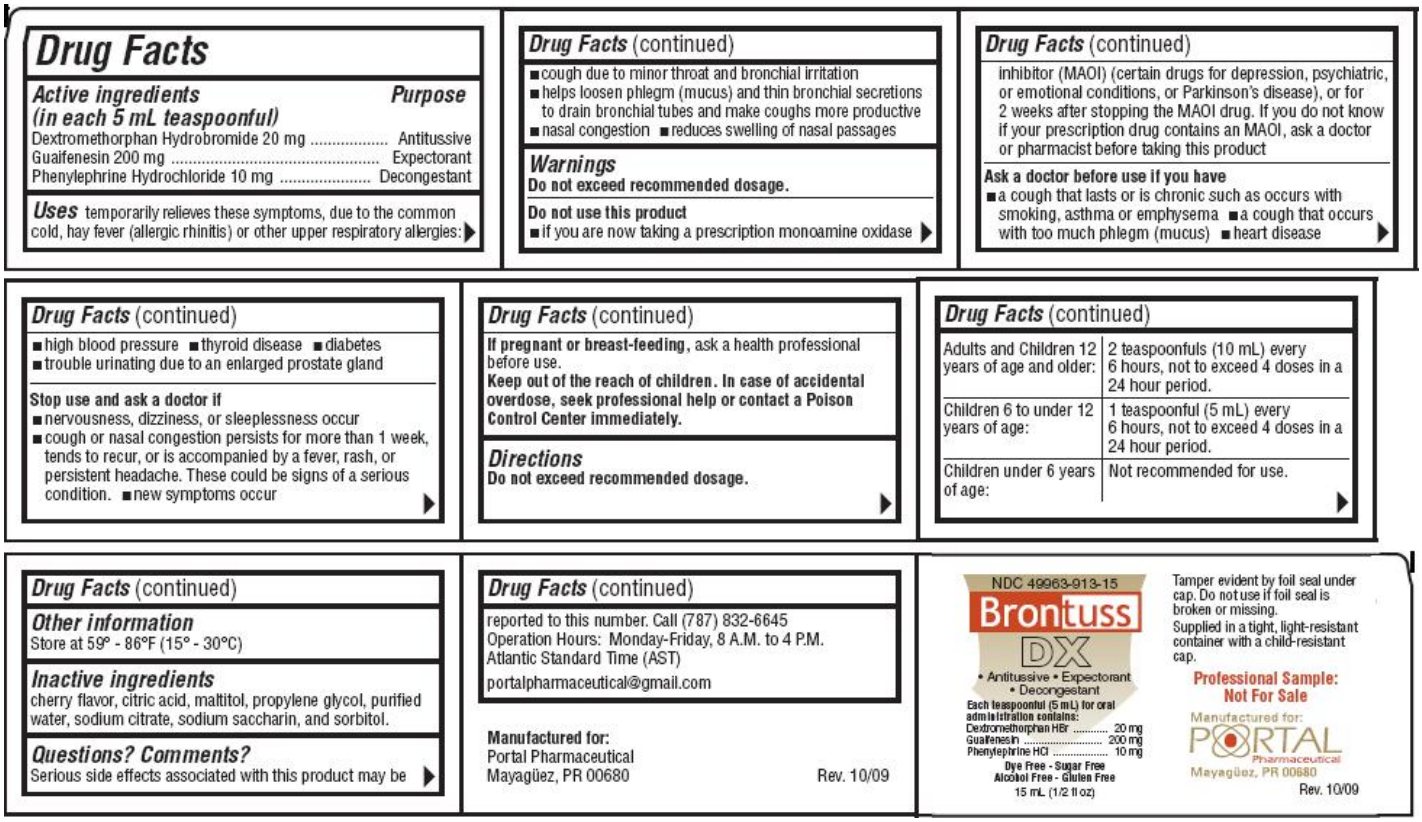
Lift Here

Supplied in a tight, light-resistant container with a child-resistant cap.

Professional Sample: Not For Sale

Manufactured for:
PORTAL Pharmaceutical
Mayagüez, PR 00680

Rev. 10/09



BRONTUSS DX

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49963-913
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 5 mL
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	200 mg in 5 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	10 mg in 5 mL

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49963-913-04	118 mL in 1 BOTTLE		
2	NDC:49963-913-15	15 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/24/2009	

Labeler - Portal Inc. (831005199)

Revised: 12/2009 Portal Inc.