BRONTUSS SF- 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 SF Liquid

Drug Facts

Active ingredients (in each 5 mL teaspoonful)	**Purpose**
Dextromethorphan Hydrobromide 15 mg	Antitussive
Guaifenesin 300 mg	Expectorant
Phenylephrine Hydrochloride 10 mg	Nasal 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 losen 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, chronic bronchitis 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.

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

Keep out of the reach of children.
In case of overdose, get medical help or contact a Poison Control Center immediately.

Directions
Do not exceed recommended dosage.

Adults and Children 12 years of age and over:	1 teaspoonful (5 mL) every 4 hours, not to exceed 6 doses in a 24 hour period.
Children 6 to under 12 years of age:	1/2 teaspoonful (2.5 mL) every 4 hours, not to exceed 6 doses in a 24 hour period.
Children under 6 years of age:	Consult a doctor

Other Information
- Each 5mL teaspoonful contains 5 mg sodium.
- Store at 59º-86ºF(15º-30ºC)

Inactive Ingredients
citric acid, glycerin, grape flavor, propylene glycol, purified water, sodium citrate, sodium saccharin, sorbitol.

Questions? Comments?
Call your doctor for medical advise about side effects. 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)

Manufactured for: Portal Pharmaceuticals, Mayaguez, PR 00680
portalpharmaceutical@gmail.com Rev. 02/10

Product Packaging:
Packaging below represents the labeling currently used:

Principal display panel and side panel for 30 mL label:

NDC 49963-813-01

Brontuss SF Liquid

Antitussive/Expectorant/Nasal Decongestant

Each teaspoonful (5 mL) for oral administration contains:
Dextromethorphan HBr.....15 mg
Guaifenesin.....300 mg
Phenylephrine HCl.....10 mg

Dye Free/Sugar Free/Alcohol Free

1 oz. (30 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. 02/10

Principal display panel and side panel for 118 mL label:

NDC 49963-813-04

Brontuss SF Liquid

Antitussive/Expectorant/Nasal Decongestant

Each teaspoonful (5 mL) for oral administration contains:
Dextromethorphan HBr.....15 mg
Guaifenesin.....300 mg
Phenylephrine HCl.....10 mg

Dye Free/Sugar Free/Alcohol 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. 02/10

Lot: P10019 Exp. Date: 03/2012

NDC 49963-813-01

Brontuss SF Liquid

• Antitussive • Expectorant
• Nasal Decongestant

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Manufactured for:

PORTAL Pharmaceutical

Mayagüez, PR 00680

Lift Here for *Drug Facts*

Rev. 02/10

Professional Sample: Not For Sale

N 3 49963 81301 3

Drug Facts

Active ingredients (in each 5 mL teaspoonful) — ***Purpose***

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Guaifenesin 300 mg	Expectorant
Phenylephrine Hydrochloride 10 mg	Nasal Decongestant

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Drug Facts (continued)

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Drug Facts (continued)

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- high blood pressure - thyroid disease - diabetes
- trouble urinating due to an enlarged prostate gland

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- 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.

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Drug Facts (continued)

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Drug Facts (continued)

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Rev. 02/10

NDC 49963-813-01

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Manufactured for:

PORTAL Pharmaceutical

Mayagüez, PR 00680

Rev. 02/10

Professional Sample: Not For Sale

N 3 49963 81301 3

BRONTUSS SF

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49963-813
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	15 mg in 5 mL
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	300 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	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49963-813-04	118 mL in 1 BOTTLE		
2	NDC:49963-813-01	30 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/16/2010	

Labeler - Portal Inc. (831005199)

Revised: 5/2010 Portal Inc.