BRONKIDS - chlorpheniramine maleate, phenylephrine hydrochloride, dextromethorphan hydrobromide liquid
Portal Pharmaceutical

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.

Bronkids Oral Drops

Drug Facts
Active ingredients
(in each 1 mL dropperful)
Chlorpheniramine Maleate 0.6 mg
Dextromethorphan Hydrobromide 2.75 mg
Phenylephrine Hydrochloride 1.5 mg

Antihistamine
Antitussive
Nasal Decongestant

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

- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- cough due to minor throat and bronchial irritation
- nasal congestion
- reduces swelling of nasal passages

Warnings
Do not exceed recommended dosage.

Do not use this product
- 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
- a breathing problem such as chronic bronchitis
- glaucoma
- a cough that lasts or is chronic such as occurs with asthma
- a cough that occurs with too much phlegm (mucus)
- heart disease
- high blood pressure
- thyroid disease
- diabetes

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

When using this product

- 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
- cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash or persistent headache. A persistent cough may be a sign of a serious condition
- new symptoms occur

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

Directions
Administer using provided dropper.
Do not exceed recommended dosage.

Children 6 to under 12 years of age:	3 dropperfuls every 4 hours. Not to exceed 18 dropperfuls in 24 hours.
Children under 6 years of age:	Consult a physician

Other information
Store at 20°-25°C (68°-77°F)
Excursions permitted to 15°-30°C (59°-86°F)

Inactive ingredients
FD&C Blue #1, Fruit Gum Flavor, Glycerin, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol.

Questions? Comments?
Call 1-787-832-6645
Serious side effects associated with use of this product may be reported to this number.

Product Packaging
Packaging below represents the labeling currently used.

Principal display panel and side panel for 30 mL label:

NDC 49963-118-01

Antihistamine / Antitussive / Nasal Decongestant
Sugar Free / Alcohol Free

Bronkids Oral Drops

DELICIOUS BUBBLE GUM FLAVOR!

Each 1 mL (dropperful) for oral administration contains:

Chlorpheniramine Maleate.....0.6 mg
Dextromethorphan HBr.....2.75 mg
Phenylephrine HCl.....1.5 mg

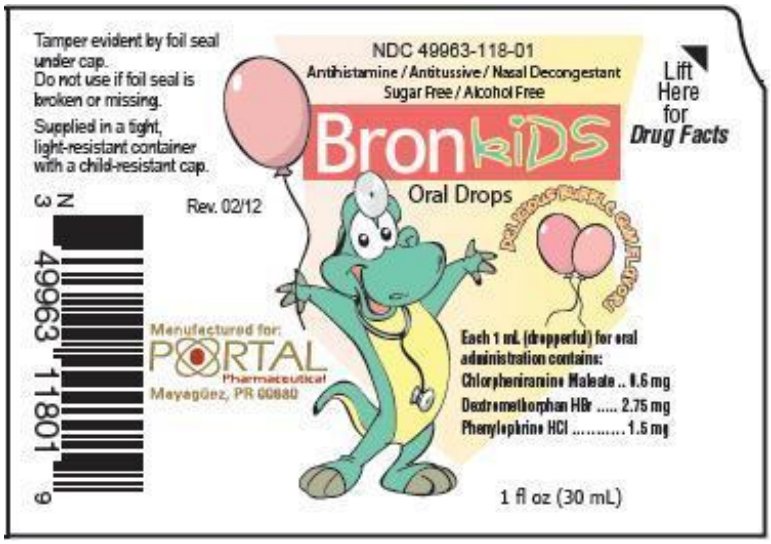
1 fl oz (30 mL)

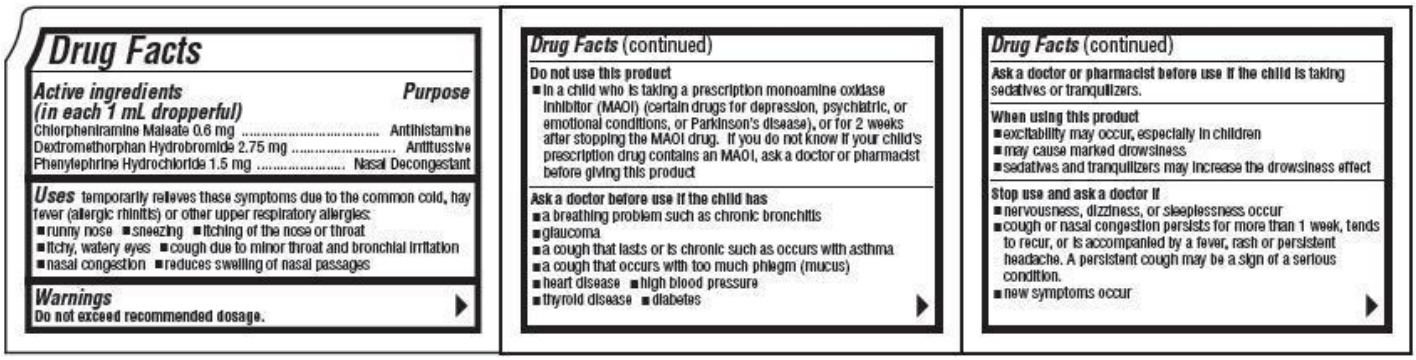
Tamper evident by foil seal under cap.
Do not use if foil seal is broken or missing.

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

Rev. 02/12

Manufactured for:
PORTAL Pharmaceutical
Mayaguez, PR 00680





BRONKIDS

chlorpheniramine maleate, phenylephrine hydrochloride, dextromethorphan hydrobromide liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49963-118
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Chlorpheniramine Maleate (UNII: V1Q0O9OJ9Z) (Chlorpheniramine - UNII:3U6IO1965U)	Chlorpheniramine Maleate	0.6 mg in 1 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	1.5 mg in 1 mL
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	2.75 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0KO0R)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Sorbitol (UNII: 506T60A25R)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/03/2007	

Labeler - Portal Pharmaceutical (831005199)

Registrant - Pernix Manufacturing, LLC (078641814)

Establishment

Name	Address	ID/FEI	Business Operations
Pernix Manufacturing, LLC dba Great Southern Laboratories		078641814	manufacture(49963-118)

Revised: 10/2012 Portal Pharmaceutical