BRONKIDS - chlorpheniramine/dextromethorphan/phenylephrine 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.

Drug Facts

Active ingredients (in each teaspoonful (5 mL)	Purpose
Chlorpheniramine Maleate 4 mg	Antihistamine
Dextromethorphan HBr 15 mg	Antitussive
Phenylephrine HCl 10 mg	Nasal Decongestant

Do not use if you are taking a prescription monoamine oxidase inhibitor (MAOI), (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease) or for two 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 or pharmacist before use if you are taking sedatives or tranquilizers.

Ask your doctor before use if you have

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

When using this product

- do not exceed recommended dosage
- may cause excitability especially in children
- may cause drowsiness: alcohol, sedatives,tranquilizers may increase the drowsiness effect
- avoid alcoholic beverages while taking this product
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- symptoms do not improve within 7 days, tend to recur or are accompanied by fever and rash or persistent headache. These may be symptoms 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 right away.

Uses temporarily relieves these symptoms due to cold, hay fever or other upper respiratory allergies

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

Questions? Reports of serious side effects
associated with use of the product call 787-832-6645.

BRONKIDS

chlorpheniramine/dextromethorphan/phenylephrine liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49963-210
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	STRAWBERRY (STRAWBERRY)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49963-210-04	118 mL in 1 BOTTLE, PLASTIC		
2	NDC:49963-210-01	30 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/01/2009	

Labeler - Portal Pharmaceutical (831005199)

Registrant - Elge Inc (610655136)

Establishment

Name	Address	ID/FEI	Business Operations
Elge Inc		610655136	manufacture

Revised: 1/2010 Portal Pharmaceutical