

**BROMPHENIRAMINE MALEATE, PSEUDOEPHEDRINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE- brompheniramine maleate, pseudoephedrine hydrochloride and dextromethorphan hydrobromide syrup**  
**Paddock Laboratories, LLC**

**Brompheniramine Maleate, Pseudoephedrine Hydrochloride and Dextromethorphan Hydrobromide Syrup**

**Rx only**

**DESCRIPTION**

Brompheniramine Maleate, Pseudoephedrine Hydrochloride and Dextromethorphan Hydrobromide Syrup is a clear, light pink syrup with a butterscotch flavor.

**Each 5 mL (1 teaspoonful) contains:**

Brompheniramine Maleate, USP ..... 2 mg

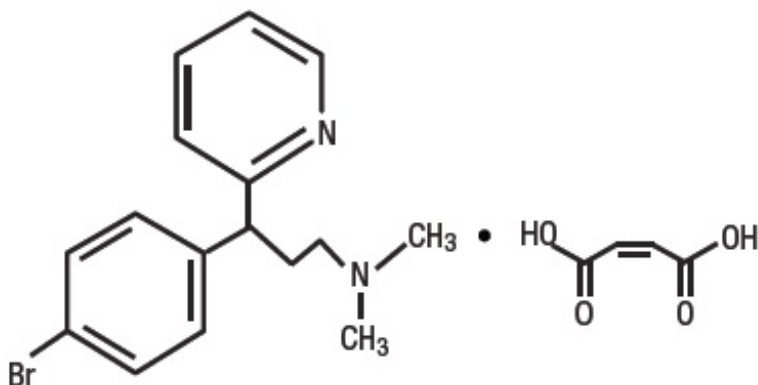
Pseudoephedrine Hydrochloride, USP ..... 30 mg

Dextromethorphan Hydrobromide, USP ..... 10 mg

Alcohol 0.95% v/v

In a palatable, aromatic vehicle.

Inactive Ingredients: alcohol, artificial butterscotch flavor, citric acid anhydrous, glycerin, methylparaben, propylene glycol, purified water, sodium benzoate, sodium citrate, sucrose, and FD&C Red No. 40. It may contain 10% citric acid solution or 10% sodium citrate solution for pH adjustment. The pH range is between 3.0 and 6.0.



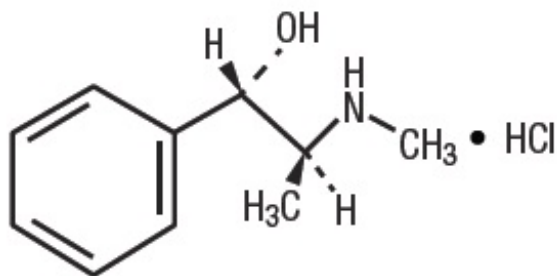
$C_{16}H_{19}BrN_2 \cdot C_4H_4O_4$

M.W. 435.31

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**Brompheniramine Maleate, USP**  
**(±)-2-p-Bromo-α-2-(dimethylamino)ethylbenzylpyridine maleate (1:1)**

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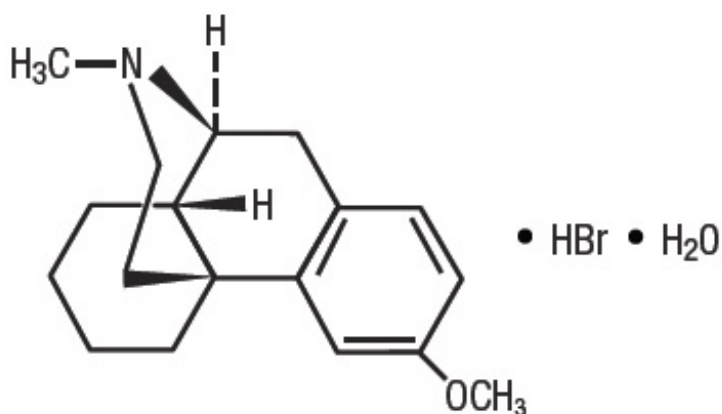
$C_{10}H_{15}NO \cdot HCl$

M.W. 201.69

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**Pseudoephedrine Hydrochloride, USP**  
**(+)-Pseudoephedrine hydrochloride**

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$C_{18}H_{25}NO \cdot HBr \cdot H_2O$

M.W. 370.32

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**Dextromethorphan Hydrobromide, USP**  
**3-Methoxy-17-methyl-9α, 13α, 14α-morphinan hydrobromide monohydrate**

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Antihistamine/Nasal Decongestant/Antitussive syrup for oral administration.

### CLINICAL PHARMACOLOGY

Brompheniramine maleate is a histamine antagonist, specifically an  $H_1$ -receptor-blocking agent belonging to the alkylamine class of antihistamines. Antihistamines appear to compete with histamine for receptor sites on effector cells. Brompheniramine also has anticholinergic (drying) and sedative effects. Among the antihistaminic effects, it antagonizes the allergic response (vasodilation, increased vascular permeability, increased mucus secretion) of nasal tissue. Brompheniramine is well absorbed from the gastrointestinal tract, with peak plasma concentration after single, oral dose of 4 mg reached in 5 hours; urinary excretion is the major route of elimination, mostly as products of biodegradation; the liver is assumed to be the main site of metabolic transformation.

Pseudoephedrine acts on sympathetic nerve endings and also on smooth muscle, making it useful as a nasal decongestant. The nasal decongestant effect is mediated by the action of pseudoephedrine on  $\alpha$ -sympathetic receptors, producing vasoconstriction of the dilated nasal arterioles. Following oral administration, effects are noted within 30 minutes with peak activity occurring at approximately one hour.

Dextromethorphan acts centrally to elevate the threshold for coughing. It has no analgesic or addictive properties. The onset of antitussive action occurs in 15 to 30 minutes after administration and is of long duration.

## **INDICATIONS AND USAGE**

For relief of coughs and upper respiratory symptoms, including nasal congestion, associated with allergy or the common cold.

## **CONTRAINDICATIONS**

Hypersensitivity to any of the ingredients. Do not use in the newborn, in premature infants, in nursing mothers, or in patients with severe hypertension or severe coronary artery disease. Do not use dextromethorphan in patients receiving monoamine oxidase (MAOI) inhibitors (*see Drug Interactions*).

Antihistamines should not be used to treat lower respiratory tract conditions including asthma.

## **WARNINGS**

Especially in infants and small children, antihistamines in overdosage may cause hallucinations, convulsions, and death.

Antihistamines may diminish mental alertness. In the young child, they may produce excitation.

## **PRECAUTIONS**

### **General**

Because of its antihistamine component, Brompheniramine Maleate, Pseudoephedrine Hydrochloride and Dextromethorphan Hydrobromide Syrup should be used with caution in patients with a history of bronchial asthma, narrow angle glaucoma, gastrointestinal obstruction, or urinary bladder neck obstruction. Because of its sympathomimetic component, Brompheniramine Maleate, Pseudoephedrine Hydrochloride and Dextromethorphan Hydrobromide Syrup should be used with caution in patients with diabetes, hypertension, heart disease, or thyroid disease.

### **Information for Patients**

Patients should be warned about engaging in activities requiring mental alertness, such as driving a car or operating dangerous machinery.

### **Drug Interactions**

Monoamine oxidase (MAO) inhibitors

Hyperpyrexia, hypotension, and death have been reported coincident with the coadministration of MAO inhibitors and products containing dextromethorphan. In addition, MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines and may enhance the effect of pseudoephedrine. Concomitant administration of Brompheniramine Maleate, Pseudoephedrine Hydrochloride and Dextromethorphan Hydrobromide Syrup and MAO inhibitors should be avoided (*see CONTRAINDICATIONS*).

Central Nervous System (CNS) depressants

Antihistamines have additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, antianxiety agents, etc.).

Antihypertensive drugs

Sympathomimetic may reduce the effects of antihypertensive drugs.

### **Carcinogenesis, Mutagenesis, Impairment of Fertility**

Animal studies of Brompheniramine Maleate, Pseudoephedrine Hydrochloride and Dextromethorphan Hydrobromide Syrup to assess the carcinogenic and mutagenic potential or the effect on fertility have not been performed.

### **Pregnancy**

Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with Brompheniramine Maleate, Pseudoephedrine Hydrochloride and Dextromethorphan Hydrobromide Syrup. It is also not known whether Brompheniramine Maleate, Pseudoephedrine Hydrochloride and Dextromethorphan Hydrobromide Syrup can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. It should be given to a pregnant woman only if clearly needed.

Reproduction studies of brompheniramine maleate (a component of Brompheniramine Maleate, Pseudoephedrine Hydrochloride and Dextromethorphan Hydrobromide Syrup) in rats and mice at doses up to 16 times the maximum human doses have revealed no evidence of impaired fertility or harm to the fetus.

### **Nursing Mothers**

Because of the higher risk of intolerance of antihistamines in small infants generally, and in newborns and prematures in particular, Brompheniramine Maleate, Pseudoephedrine Hydrochloride and Dextromethorphan Hydrobromide Syrup is contraindicated in nursing mothers.

### **Pediatric Use**

Safety and effectiveness in pediatric patients below the age of 6 months have not been established (*see DOSAGE AND ADMINISTRATION*).

## **ADVERSE REACTIONS**

The most frequent adverse reactions to Brompheniramine Maleate, Pseudoephedrine Hydrochloride and Dextromethorphan Hydrobromide Syrup are: sedation; dryness of mouth, nose and throat; thickening of bronchial secretions; dizziness.

Other adverse reactions may include:

***Dermatologic:*** Urticaria, drug rash, photosensitivity, pruritus.

***Cardiovascular System:*** Hypotension, hypertension, cardiac arrhythmias, palpitation.

***CNS:*** Disturbed coordination, tremor, irritability, insomnia, visual disturbances, weakness, nervousness, convulsions, headache, euphoria, and dysphoria.

***G.U. System:*** Urinary frequency, difficult urination.

***G.I. System:*** Epigastric discomfort, anorexia, nausea, vomiting, diarrhea, constipation.

***Respiratory System:*** Tightness of chest and wheezing, shortness of breath.

***Hematologic System:*** Hemolytic anemia, thrombocytopenia, agranulocytosis.

## **OVERDOSAGE**

## Signs and Symptoms

Central nervous system effects from overdosage of brompheniramine may vary from depression to stimulation, especially in children. Anticholinergic effects may be noted. Toxic doses of pseudoephedrine may result in CNS stimulation, tachycardia, hypertension, and cardiac arrhythmias; signs of CNS depression may occasionally be seen. Dextromethorphan in toxic doses will cause drowsiness, ataxia, nystagmus, opisthotonos, and convulsive seizures.

## Toxic Doses

Data suggest that individuals may respond in an unexpected manner to apparently small amounts of a particular drug. A 2½-year-old child survived the ingestion of 21 mg/kg of dextromethorphan exhibiting only ataxia, drowsiness, and fever, but seizures have been reported in 2 children following the ingestion of 13 mg/kg to 17 mg/kg. Another 2½-year-old child survived a dose of 300 mg to 900 mg of brompheniramine. The toxic dose of pseudoephedrine should be less than that of ephedrine, which is estimated to be 50 mg/kg.

## Treatment

Induce emesis if patient is alert and is seen prior to 6 hours following ingestion. Precautions against aspiration must be taken, especially in infants and small children. Gastric lavage may be carried out, although in some instances tracheostomy may be necessary prior to lavage. Naloxone hydrochloride 0.005 mg/kg intravenously may be of value in reversing the CNS depression that may occur from an overdose of dextromethorphan. CNS stimulants may counter CNS depression. Should CNS hyperactivity or convulsive seizures occur, intravenous short-acting barbiturates may be indicated. Hypertensive responses and/or tachycardia should be treated appropriately. Oxygen, intravenous fluids, and other supportive measures should be employed as indicated.

## DOSAGE AND ADMINISTRATION

Adults and pediatric patients 12 years of age and over: 10 mL (2 teaspoonfuls) every 4 hours. Children 6 to under 12 years of age: 5 mL (1 teaspoonful) every 4 hours. Children 2 to under 6 years of age: 2.5 mL (½ teaspoonful) every 4 hours. Infants 6 months to under 2 years of age: Dosage to be established by a physician.

Do not exceed 6 doses during a 24-hour period.

## HOW SUPPLIED

Brompheniramine Maleate, Pseudoephedrine Hydrochloride and Dextromethorphan Hydrobromide Syrup is a clear, light pink-colored, butterscotch-flavored syrup containing in each 5 mL (1 teaspoonful) brompheniramine maleate 2 mg, pseudoephedrine hydrochloride 30 mg and dextromethorphan hydrobromide 10 mg, available in the following sizes:

4 fl oz (118 mL): NDC 0574-1104-04

1 Pint (473 mL): NDC 0574-1104-16

## RECOMMENDED STORAGE

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

## Keep Tightly Closed

Dispense in a tight, light-resistant container as defined in the USP.

## Rx Only

Manufactured By Perrigo

Minneapolis, MN 55427

2202942

0U400 RC J1

Rev 04-14 A

**PACKAGE/LABEL PRINCIPAL DISPLAY PANEL – 118 mL**

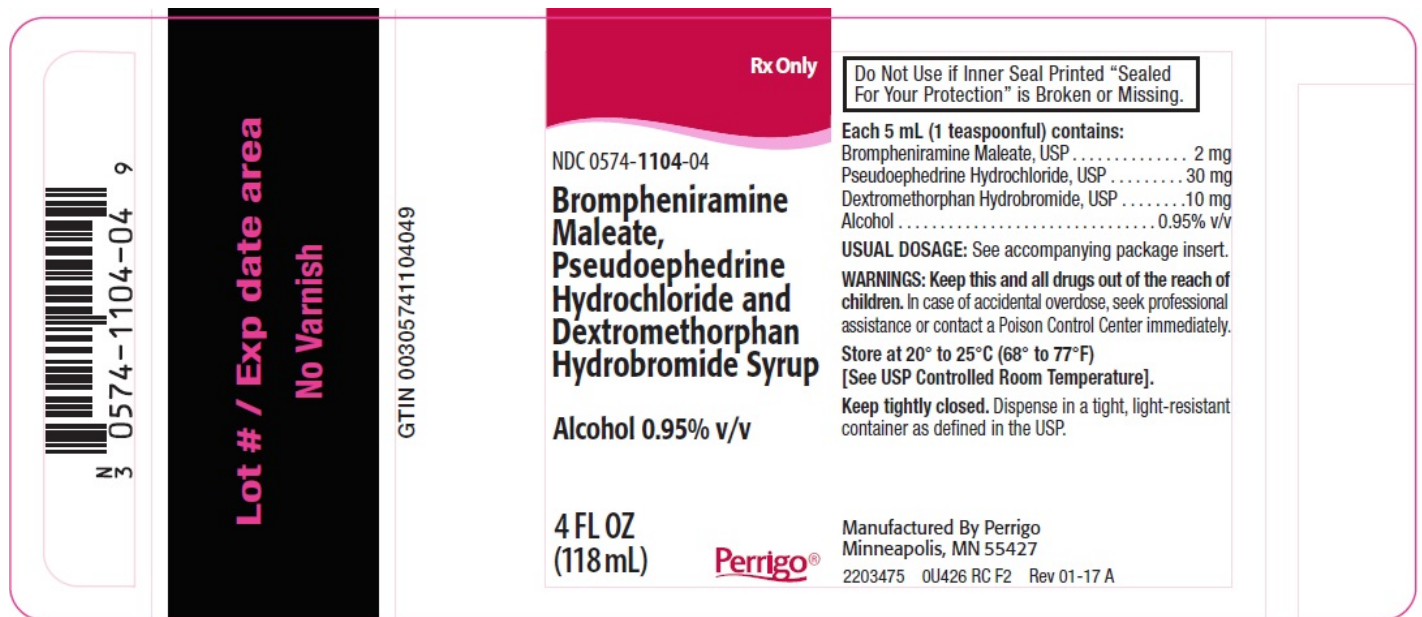
**Rx Only**

NDC 0574-1104-04

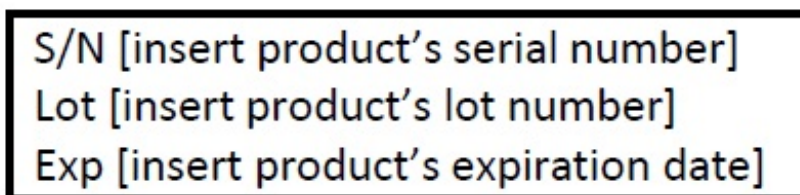
**Brompheniramine Maleate, Pseudoephedrine Hydrochloride and Dextromethorphan Hydrobromide Syrup**

**Alcohol 0.95% v/v**

**4 FL OZ (118 mL)**



The following image is a placeholder representing the product identifier that is either affixed or imprinted on the drug package label during the packaging operation.



**PACKAGE/LABEL PRINCIPAL DISPLAY PANEL – 473 mL**

**Rx Only**

NDC 0574-1104-16

**Brompheniramine Maleate, Pseudoephedrine Hydrochloride and Dextromethorphan**

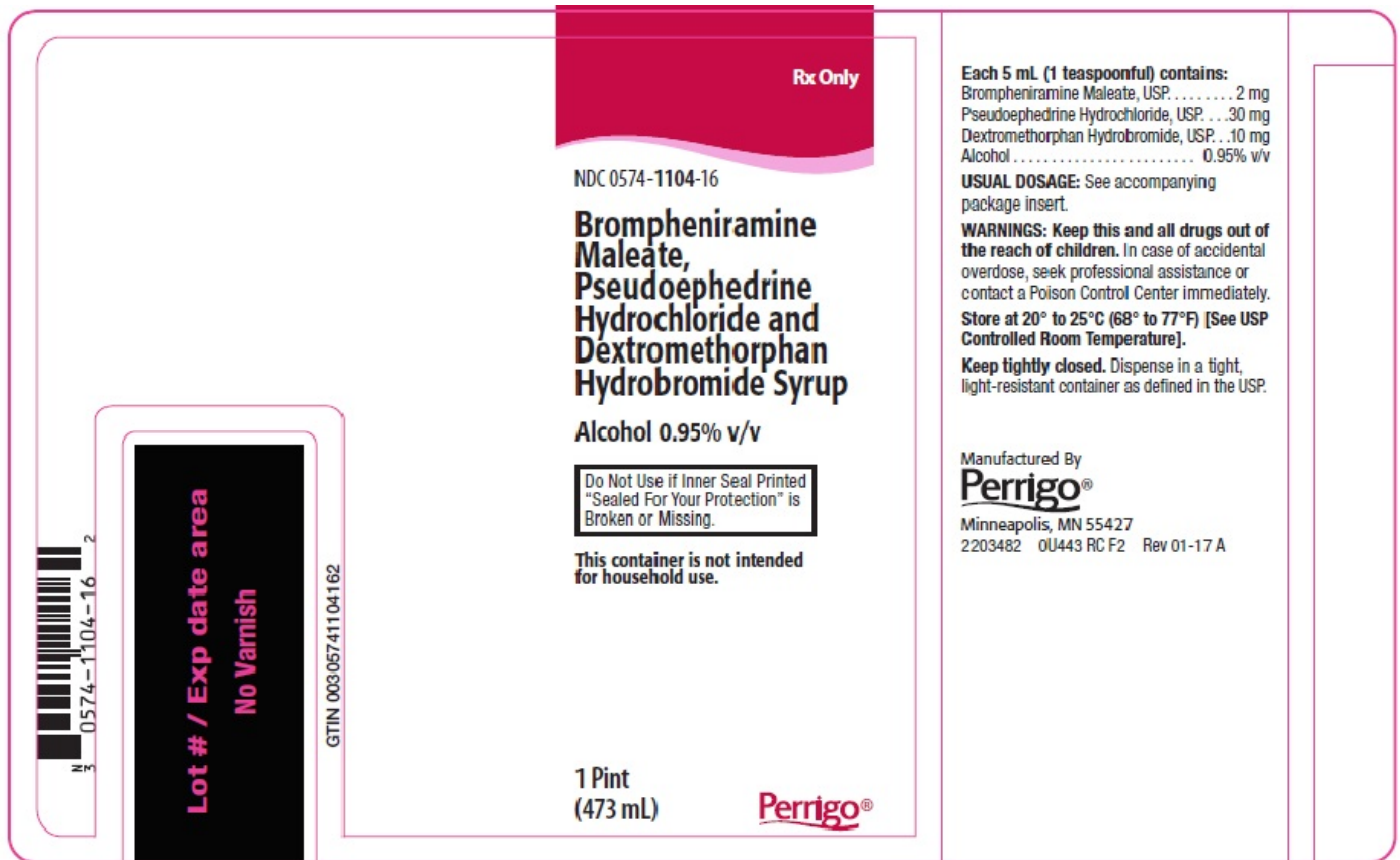
# Hydrobromide Syrup

Alcohol 0.95% v/v

Do Not Use if Inner Seal Printed “Sealed For Your Protection” is Broken or Missing.

**This container is not intended for household use.**

**1 Pint (473 mL)**



The following image is a placeholder representing the product identifier that is either affixed or imprinted on the drug package label during the packaging operation.

S/N [insert product's serial number]  
Lot [insert product's lot number]  
Exp [insert product's expiration date]

## **BROMPHENIRAMINE MALEATE, PSEUDOEPHEDRINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE**

brompheniramine maleate, pseudoephedrine hydrochloride and dextromethorphan hydrobromide syrup

### **Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0574-1104
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Route of Administration ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BROMPHENIRAMINE MALEATE</b> (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	2 mg in 5 mL
<b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg in 5 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	

### Product Characteristics

<b>Color</b>	PINK (clear, light pink)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BUTTERSCOTCH	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0574-1104-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/06/2015	
2	NDC:0574-1104-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/06/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205292	02/06/2015	

Labeler - Paddock Laboratories, LLC (967694121)



