

**PEDIACARE-COUGH-RUNNYNOSE- acetaminophen, chlorpheniramine maleate, dextromethorphan liquid**  
**Strides Pharma 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.*

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**PEDIACARE CHILDRENS COUGH AND RUNNY NOSE- acetaminophen, chlorpheniramine maleate and dextromethorphan hydrobromide liquid**

**Drug Facts**

**Active ingredients**

*(in each 5 mL)*

Acetaminophen 160 mg

Chlorpheniramine maleate 1 mg

Dextromethorphan HBr 5 mg

**Purpose**

Acetaminophen 160 mg.....Fever reducer/Pain reliever

Chlorpheniramine maleate 1 mg.....Antihistamine

Dextromethorphan HBr 5 mg.....Cough suppressant

**Uses**

temporarily relieves the following cold/flu symptoms:

- minor aches and pains
- cough
- headache
- sore throat
- sneezing and runny nose
- temporarily reduces fever

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if the child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**Do not use**

- to make a child sleepy
- 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.
- with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if the child is allergic to any of the ingredients in this product.

**Ask a doctor before use if the child has**

- glaucoma
- liver disease
- a breathing problem such as chronic bronchitis
- cough that occurs with excessive phlegm (mucus)
- persistent or chronic cough such as occurs with asthma

**Ask a doctor or pharmacist before use if child is taking**

- sedatives or tranquilizers
- the blood thinning drug warfarin

**When using this product**

- **do not exceed recommended dosage (see overdose warning)**
- may cause excitability, especially in children
- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness

**Stop use and ask a doctor if**

- new symptoms occur
- fever gets worse or lasts for more than 3 days
- redness or swelling is present
- pain or cough gets worse or lasts for more than 5 days
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition

**Keep out of reach of children**

**Overdose Warning**

Taking more than the recommended dose (overdose) could cause serious health problems, including liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

**Directions**

- **do not exceed recommended dosage (see overdose warning)**

- **do not use in infants**
- **this product does not contain directions or complete warnings for adult use.**
- **shake well before using**
- use only the dosing cup provided
- find right dose on chart below. If possible, use weight to dose; otherwise, use age
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- mL = milliliter

<b>Weight (lbs)</b>	<b>Age (yrs)</b>	<b>Dose (mL)</b>
under 36	under 4	do not use
36 - 47	4 - 5	do not use unless directed by a doctor
48-95	6-11	10 mL

#### **Other information**

- dosage cup provided
- store at room temperature
- **Tamper Evident: Do not use if printed safety seal on the bottle is broken or missing.**

#### **Inactive ingredients**

citric acid, FD&C red no.40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose / carboxymethylcellulose sodium, potassium sorbate, purified water, sorbitol, sucralose, xanthan gum.

#### **Questions?**

**1-888-474-3099**

Monday - Friday 8 am to 8 pm EST

**PediaCare.com**

#### **PRINCIPAL DISPLAY PANEL**

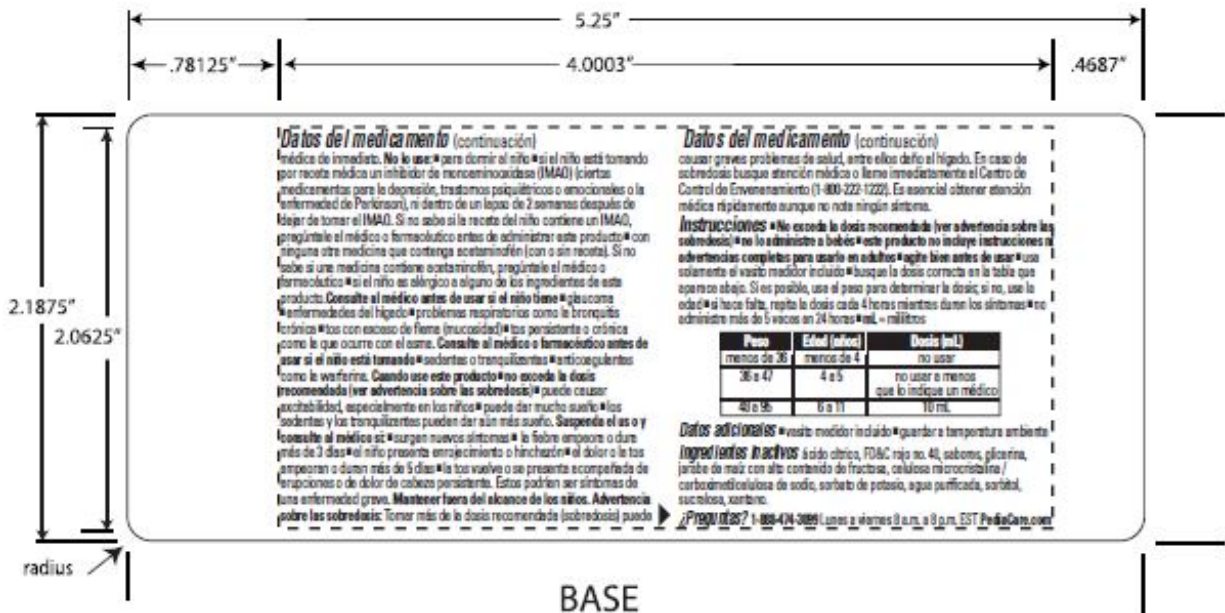
**PediaCare® Children Cough & Runny Nose**

**Fever, Sore Throat & Sneezing**

4 FL OZ FL (118 mL)

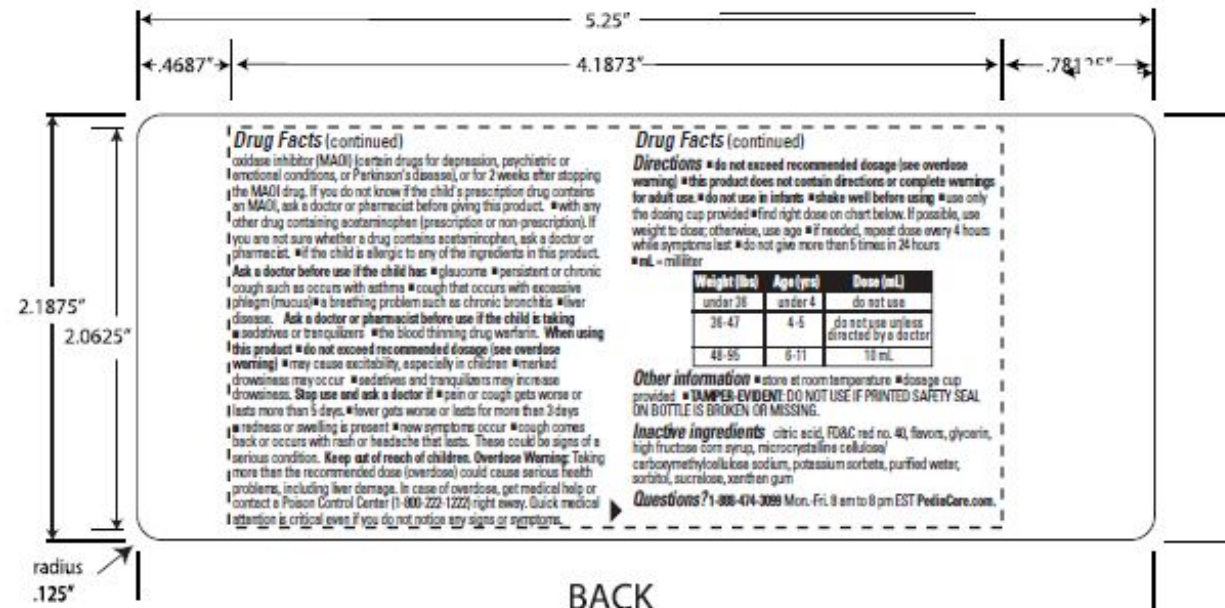
**Cherry Flavor**





BASE

Container Label - Base



BACK

Container Label - Back

<b>PEDIACARE-COUGH-RUNNYNOSE</b> acetaminophen, chlorpheniramine maleate, dextromethorphan liquid			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59556-852
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
			160 mg

<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	100 mg in 5 mL
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	1 mg in 5 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY (Cherry Flavor)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59556-852-58	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2010	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/09/2010	

**Labeler** - Strides Pharma Inc (078868278)

### Establishment

Name	Address	ID/FEI	Business Operations
Fareva Richmond, Inc.		969523245	MANUFACTURE(59556-852) , ANALYSIS(59556-852) , LABEL(59556-852) , PACK(59556-852)