PEDIACARE MULTI SYMPTOM COLD- acetaminophen,chlorpheniramine maleate,dextromethorphan hbr,phenylephrine hcl 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.

PEDIACARE CHILDRENS MULTI SYMPTOM COLD - acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide and phenylephrine hydrochloride liquid

Drug Facts

Active ingredients

(in each 5 mL)

Acetaminophen 160 mg

Chlorpheniramine maleate 1 mg

Dextromethorphan HBr 5 mg

Phenylephrine HCl 2.5 mg

Purposes

Acetaminophen 160 mg…….. Fever reducer/ pain reliever

Chlorpheniramine maleate 1 mg….Antihistamine

Dextromethorphan HBr 5 mg……Cough Suppressant

Phenylephrine HCl 2.5 mg…… Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
- minor aches and pains
- headache
- sore throat
- stuffy nose
- cough
- sneezing and runny nose
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Sever liver damage may occur if your child takes:

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

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.

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.

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 nonprescription). 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
- thyroid disease
- diabetes
- high blood pressure
- heart disease
- a breathing problem such as chronic bronchitis
- persistent or chronic cough such as occurs with asthma
- cough that occurs with excessive phlegm (mucus)
- liver disease

Ask a doctor or pharmacist before use if child is

- taking sedatives or tranquilizers
- taking 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

- nervousness, dizziness or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present
- 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 take more than directed (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 provided dosing cup
- 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 = millilitre

Weight (lbs)	Age (yrs)	Dose (mL)
under 36	under 4	do not use
36 - 47	4 to under 6	do not use unless directed by doctor
48 - 95	6 - 11	10 mL

Other information

- dosage cup provided
- store at 20°-25°C (68°-77°F)
- **Tamper Evident: Do not use if printed safety seal on the bottle is broken or missing**

Inactive ingredients

carboxymethylcellulose sodium, citric acid (anhydrous), FD&C blue no.1, FD&C red no.40, flavors, glycerin, microcrystalline cellulose, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

***Questions*? 1-888-474-3099**

PediaCare.com

PRINCIPAL DISPLAY PANEL

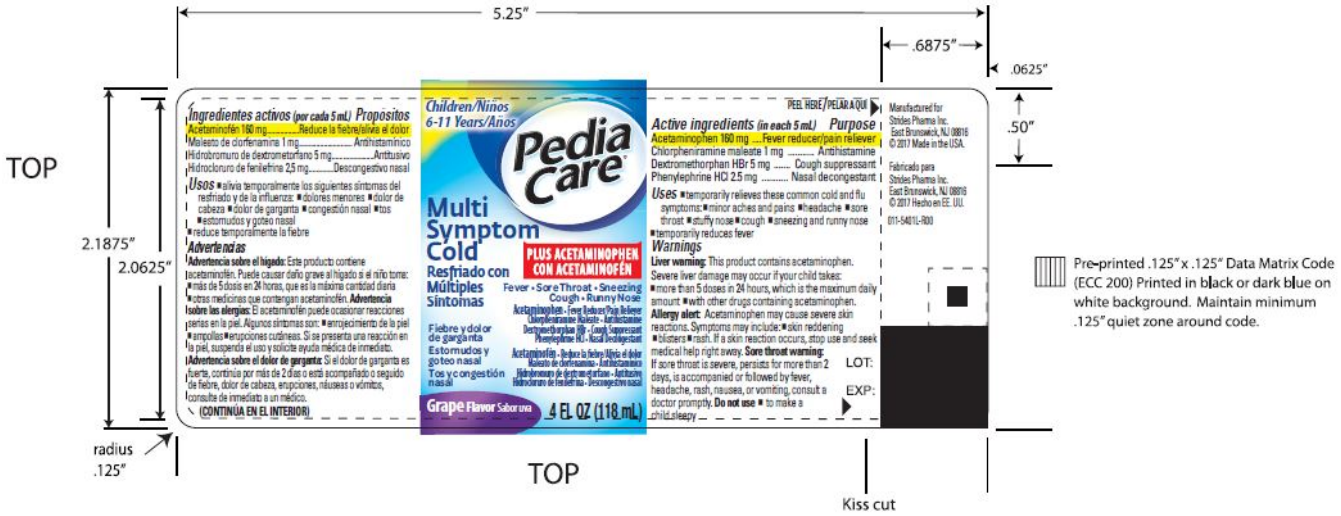
PediaCare Multi Symptom Cold

Plus Acetaminophen

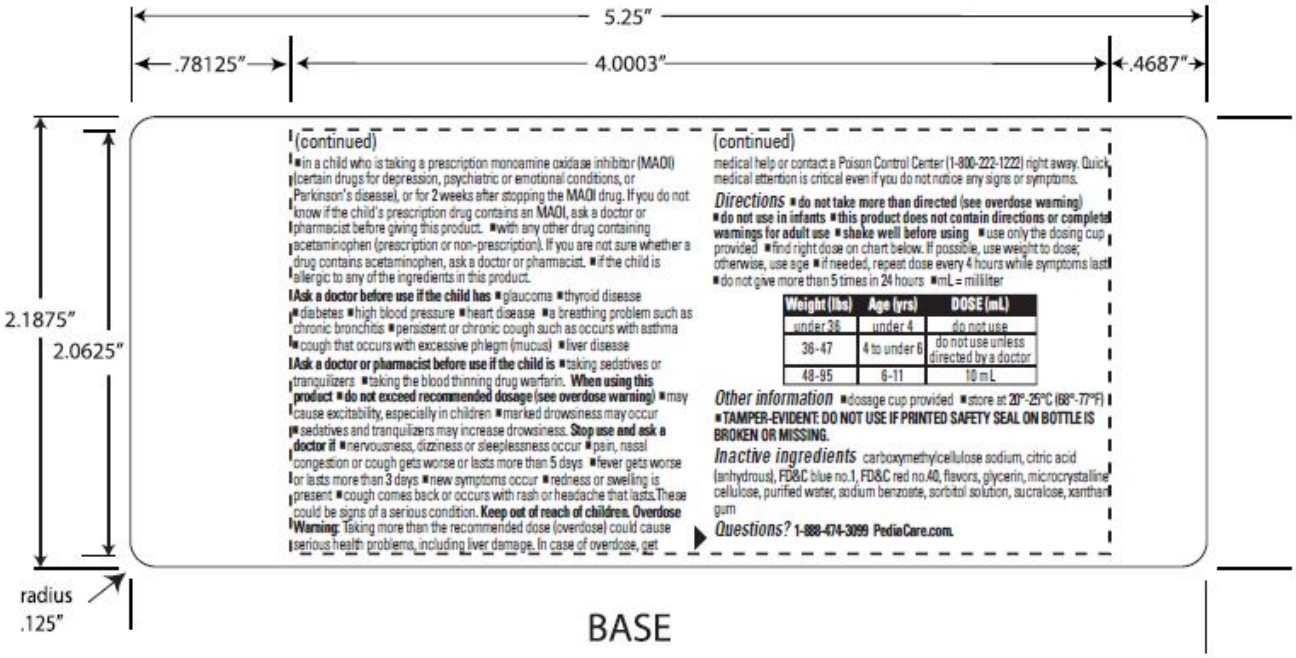
Grape Flavor

4 FL OZ (118 mL)

Carton



Container Label - Top



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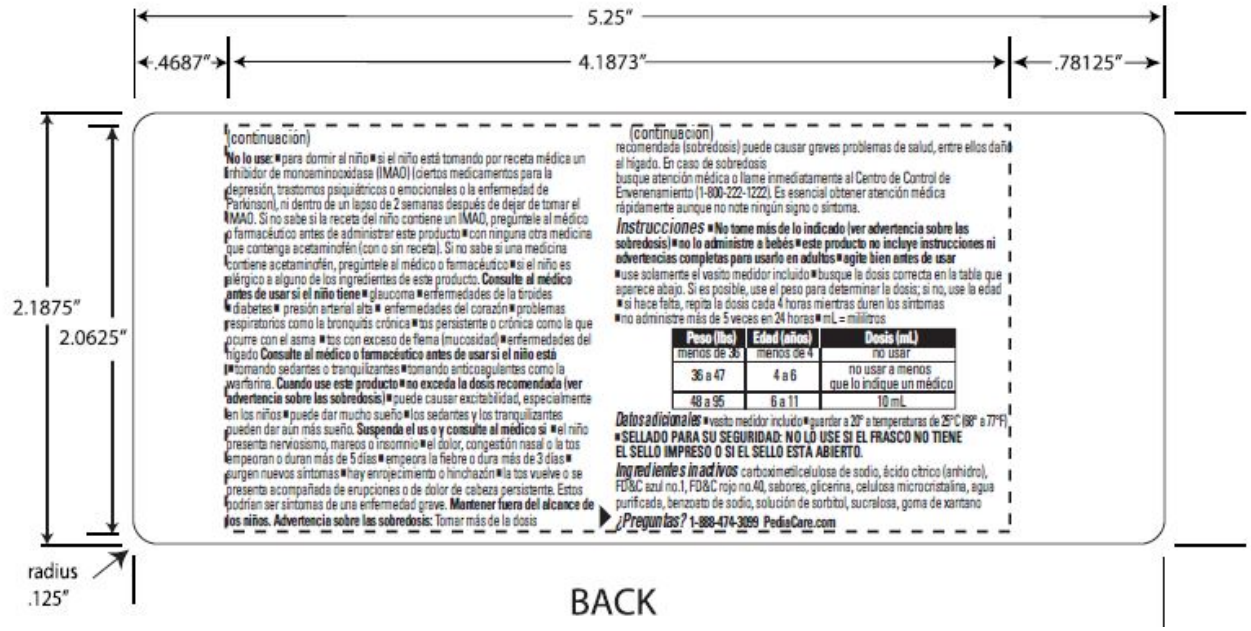

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PEDIACARE MULTI SYMPTOM COLD

acetaminophen,chlorpheniramine maleate,dextromethorphan hbr,phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59556-851
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	1 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	GRAPE (Grape Flavor)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59556-851-58	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(59556-851) , ANALYSIS(59556-851) , LABEL(59556-851) , PACK(59556-851)