PEDIACARE CHILDRENS COUGH AND CONGESTION- dextromethorphan hydrobromide and guaifenesin 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 COUGH AND CONGESTION - dextromethorphan hydrobromide and guaifenesin liquid

Drug Facts

Active ingredients

(in each 5 mL)

Dextromehorphan HBr, 5 mg

Guaifenesin, 100 mg

Purpose

Dextromehorphan HBr, 5 mg…….Cough suppressant

Guaifenesin, 100 mg……..Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - the impulse to cough to help your child get to sleep

Warnings

Do not use for 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

- cough that occurs with excessive phlegm (mucus)
- persistent or chronic cough such as occurs with asthma or chronic bronchitis

Stop use and ask a doctor if

- cough gets worse or last more than 7 days
- cough comes back or occurs with fever, rash, or persistent headache.

These could be signs of a serious illness.

When using this product do not use more than directed

Keep out of reach of children

In case of overdose, seek medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- **this product does not contain directions or complete warnings for adult use**
- use only the dosing cup provided
- do not exceed 6 doses in a 24-hour period
- mL = milliliter

Age (yrs)	Dose (ml)
under 4 years	do not use
4 to under 6 yrs	2.5-5 mL every 4 hours
6 to 11 yrs	5-10 mL every 4 hours

Other information

- each 5 mL contains:**sodium 3 mg**
- store at room temperature
- dosage cup provided

Inactive ingredients

acesulfame potassium, citric acid, FD&C red no. 33, FD&C red no. 40, flavors, glycerin, monoammonium glycyrrhizinate, poloxamer 407, potassium sorbate, propylene glycol, purified water, sodium chloride, sodium citrate, sucralose, sucrose

Questions?

1-888-474-3099

Monday - Friday 8 am to 8 pm EST

PediaCare.com

PRINCIPAL DISPLAY PANEL

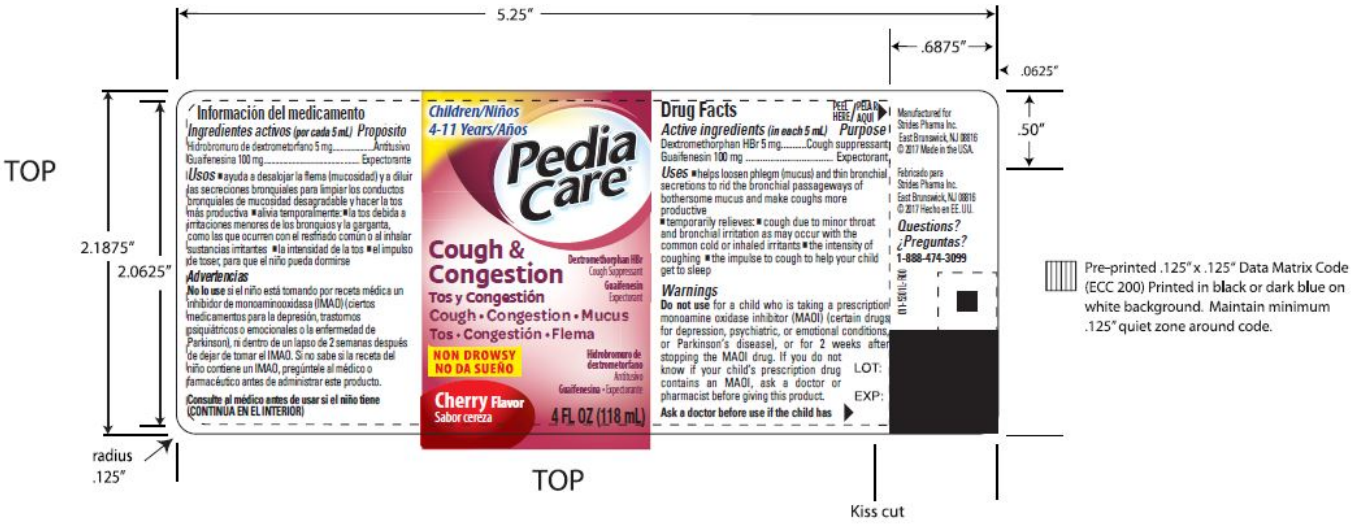
PediaCare® Children Cough & Congestion

Non Drowsy

4 FL OZ FL (118 mL)

Cherry Flavor

Carton



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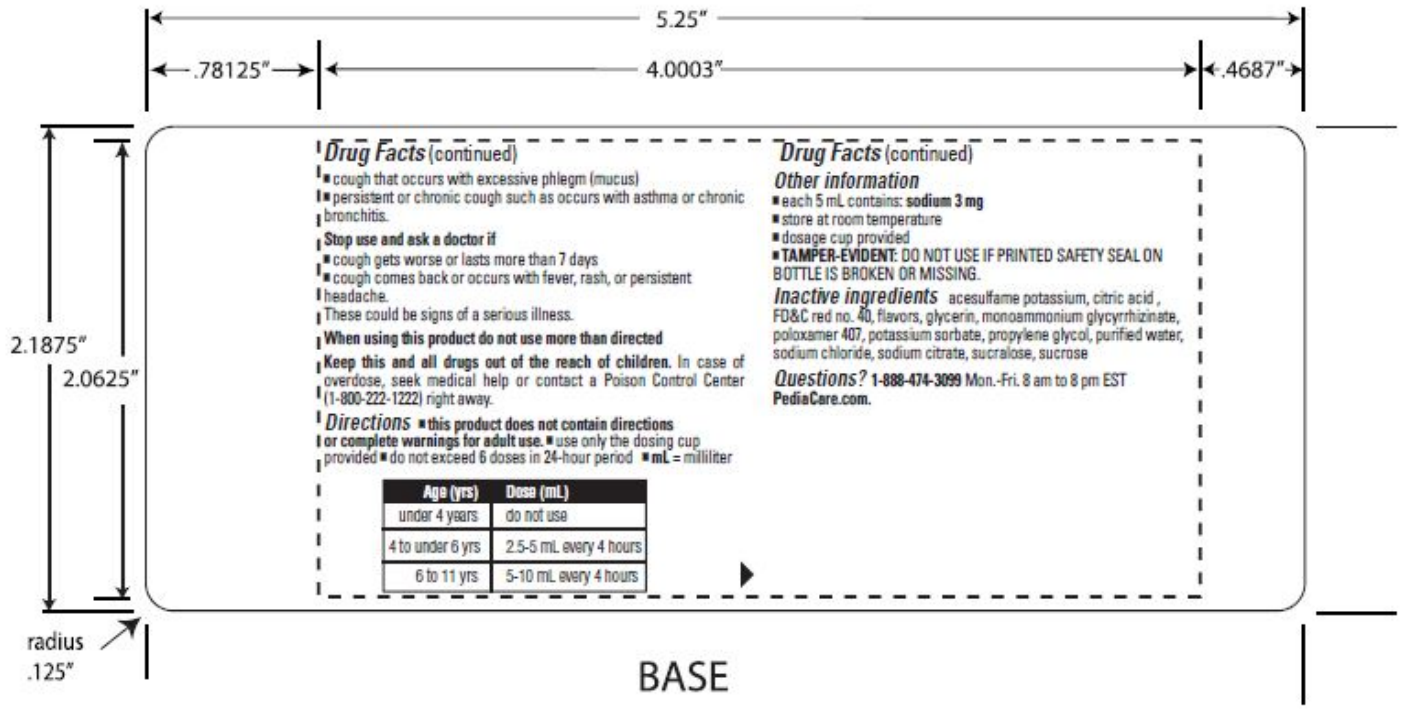

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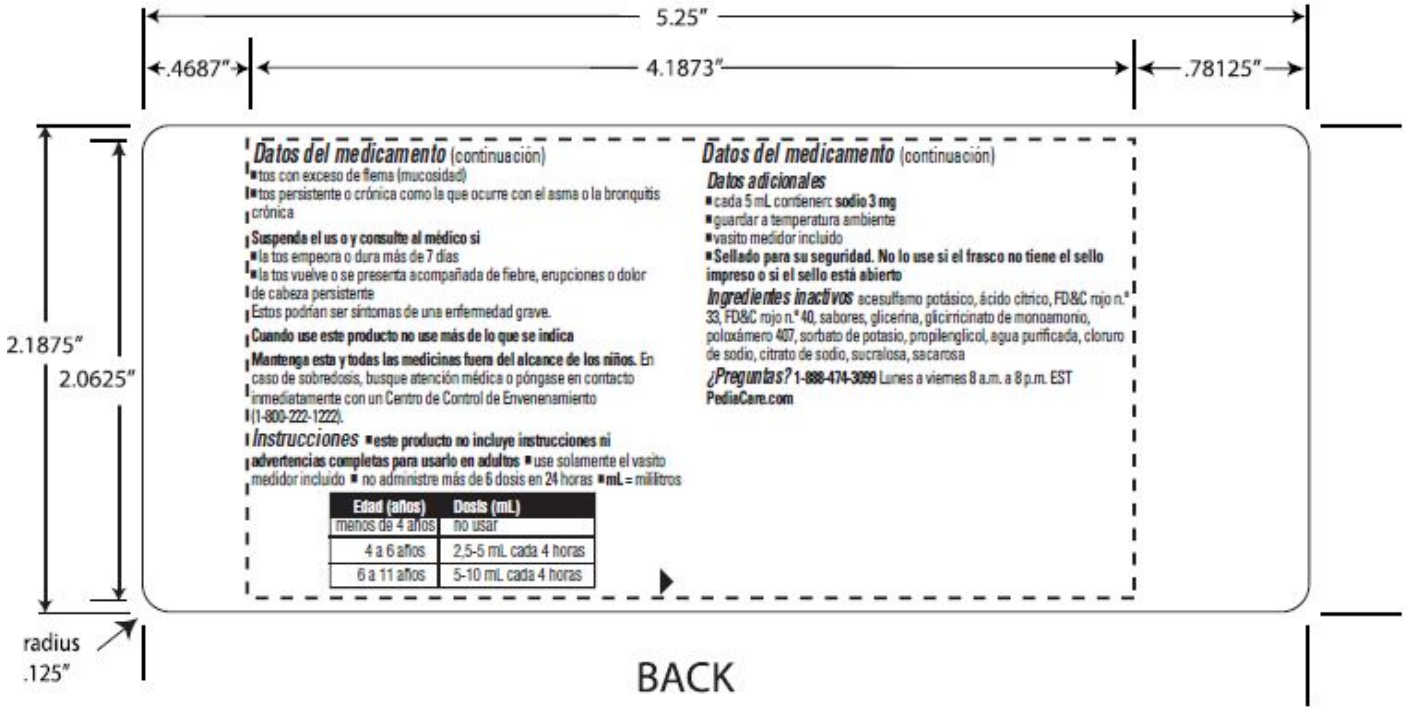

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PEDIACARE CHILDRENS COUGH AND CONGESTION

dextromethorphan hydrobromide and guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59556-850
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	CHERRY (Cherry Flavor)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59556-850-58	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/12/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/12/2010	

Labeler - Strides Pharma Inc (078868278)

Establishment

Name	Address	ID/FEI	Business Operations
Fareva Richmond, Inc.		969523245	MANUFACTURE(59556-850) , ANALYSIS(59556-850) , LABEL(59556-850) , PACK(59556-850)

Revised: 8/2017

Strides Pharma Inc