CHILDRENS MUCINEX MULTI-SYMPTOM COLD AND FEVER- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution
Reckitt Benckiser LLC

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.

Children's
Mucinex®
Multi-Symptom
Cold & Fever

Drug Facts

Active ingredients (in each 10 mL)	***Purposes***
Acetaminophen 325 mg	**Pain reliever/fever reducer**
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
  - nasal congestion
  - stuffy nose
  - cough due to minor throat and bronchial irritation
  - the intensity of coughing
  - the impulse to cough to help your child get to sleep
  - minor aches and pains
  - sore throat
  - headache
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Liver warning

This product contains acetaminophen. Severe 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

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

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

- 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.

Ask a doctor before use if your child has
- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- a breathing problem such as chronic bronchitis
- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin

When using this product do not use more than directed **(see Overdose warning)**

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
- redness or swelling is present
- new symptoms occur
- 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) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions
- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed (see Overdose warning)**
- do not give more than 5 doses in any 24-hour period
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 days unless directed by a doctor
- **shake well before using**
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- mL = milliliter
- children 6 to under 12 years of age: 10 mL in dosing cup provided
- children under 6 years of age: do not use

Other information

- each 10 mL contains: **sodium 6 mg**
- tamper evident: do not use if neckband on bottle cap is broken or missing.
- store between 20-25°C (68-77°F)
- do not refrigerate
- dosing cup provided

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C Blue #1, FD&C Red #40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate,[1] xanthan gum

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[1] may contain this ingredient

Questions?

1-866-MUCINEX (1-866-682-4639) You may also report side effects to this phone number.

Dist. by: Reckitt Benckiser
Parsippany, NJ 07054-0224

Made in England

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

NDC 63824-017-64

Children's
Mucinex®

Multi-Symptom
Cold & Fever

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- **Fever**
- **Cough**
- **Stuffy Nose**
- **Chest Congestion**
- **Breaks up Mucus**

Age 6+

Berry Blast
Flavor Liquid

4 FL OZ
(118 mL)

Tamper evident: do not use if neckband on bottle cap is broken or missing.

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Mucinex

Multi-Symptom Cold & Fever

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NDC 63824-017-64

Drug Facts (continued)

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Children's
Mucinex

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- ✓ Fever
- ✓ Cough
- ✓ Stuffy Nose
- ✓ Chest Congestion
- ✓ Breaks up Mucus

Age 6+

Berry Blast Flavor Liquid

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

3 63824 01764 8

LOT CODE:
EXP. DATE:

3000452

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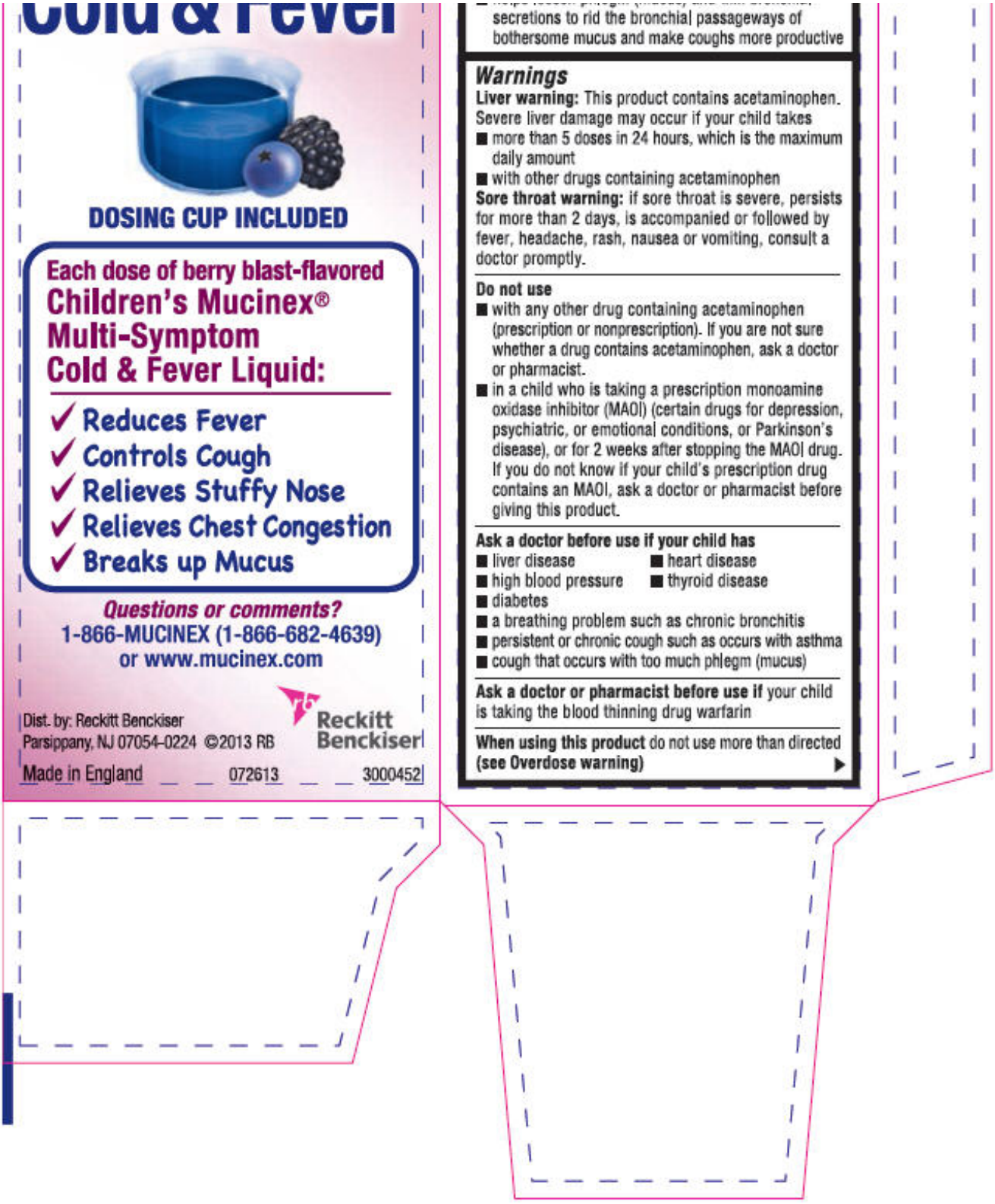

CHILDRENS MUCINEX MULTI-SYMPTOM COLD AND FEVER

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63824-017
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
acetaminophen (UNII: 362O9ITL9D) (acetaminophen - UNII:362O9ITL9D)	acetaminophen	650 mg in 20 mL
dextromethorphan hydrobromide (UNII: 9D2RTI9KYH) (dextromethorphan - UNII:7355X3ROTS)	dextromethorphan hydrobromide	20 mg in 20 mL
guaifenesin (UNII: 495W7451VQ) (guaifenesin - UNII:495W7451VQ)	guaifenesin	400 mg in 20 mL
phenylephrine hydrochloride (UNII: 04JA59TNSJ) (phenylephrine - UNII:1WS297W6MV)	phenylephrine hydrochloride	10 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
edetate disodium (UNII: 7FLD91C86K)	
FD&C Blue NO. 1 (UNII: H3R47K3TBD)	
FD&C Red NO. 40 (UNII: WZB9127XOA)	
glycerin (UNII: PDC6A3C0OX)	
propylene glycol (UNII: 6DC9Q167V3)	
propyl gallate (UNII: 8D4SNN7V92)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitol (UNII: 506T60A25R)	
sucralose (UNII: 96K6UQ3ZD4)	
trisodium citrate dihydrate (UNII: B22547B95K)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	BLUE	**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-017-64	1 in 1 CARTON	04/04/2011	
1		118 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	04/04/2011	

Labeler - Reckitt Benckiser LLC (094405024)

Revised: 9/2016 Reckitt Benckiser LLC