# MUCINEX CHILDRENS FEVER SORE THROAT AND COUGH- acetaminophen, dextromethorphan hydrobromide solution RB Health (US) LLC

-----

# Mucinex Children's Fever, Sore Throat & Cough

### **Drug Facts**

# Active ingredients / Purpose (in each 10 mL)

Acetaminophen 325 mg..Pain reliever/fever reducer Dextromethorphan HBr 10 mg....Cough suppressant

Acetaminophen 325 mg..Pain reliever/fever reducer Dextromethorphan HBr 10 mg....Cough suppressant

#### **Uses**

- 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
- minor aches and pains
- sore throat
- headache
- temporarily reduces fever

# 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 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

- 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 the child has

- liver disease
- chronic cough that lasts such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

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

# Stop use and ask a doctor if

- pain 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**

#### **Directions**

■ this product does not contain directions or complete warnings for adult use

- do not give more than directed (see Overdose warning)
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- children 6 to under 12 years of age: 10 mL in dosing cup provided every 4 hours while symptoms last; do not give more than 5 doses in any 24-hour period
- children under 6 years of age: do not use

### Other information

- each 10 mL contains: sodium 6 mg
- store at 20-25°C (68-77°F)
- do not refrigerate

**Inactive ingredients:** anhydrous citric acid, D&C yellow no. 10, edetate disodium, FD&C red no. 40, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions? 1-866-682-4639

NDC 72854-064

Children's Mucinex®

Honey Flavor Liquid

4 FL OZ (118 mL)



#### MUCINEX CHILDRENS FEVER SORE THROAT AND COUGH

acetaminophen, dextromethorphan hydrobromide solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72854-064
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg in 10 mL	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL	

Inactive Ingredients		
Ingredient Name	Strength	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		

D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
XANTHAN GUM (UNII: TTV12P4NEE)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics			
Color	yellow	Score	
Shape		Size	
Flavor	HONEY	Imprint Code	
Contains			

F	Packaging			
#	t ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72854- 064-04	1 in 1 CARTON	05/01/2024	
1	L	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 Drug	M012	05/01/2024	

# Labeler - RB Health (US) LLC (081049410)

Revised: 4/2024 RB Health (US) LLC