## MUCINEX CHILDRENS MIGHTY CHEWS NIGHT TIME COLD AND FLUacetaminophen, dextromethorphan hbr and doxylamine succinate tablet, chewable

RB Health (US) LLC

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### Mucinex Children's Mighty Chews Cough Nighttime

### **Drug Facts**

Dextromethorphan HBr 10 mg Doxylamine succinate 6.25 mg

Dextromethorphan HBr 10 mg......Cough suppressant Doxylamine succinate 6.25 mg.....Antihistamine

#### Uses

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- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- controls cough to help you get to sleep
- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- runny nose sneezing
- itching of the nose or throat itchy, watery eyes

## **Warnings**

#### Do not use

- to make a child sleepy
- if you are now 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 prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

## Ask a doctor before use if you have

- a sodium-restricted diet glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)

## Ask a doctor or pharmacist before use if you are

■ taking sedatives or tranquilizers

## When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness

- avoid alcoholic drinks
- use caution when driving a motor vehicle or operating machinery

## Stop use and ask a doctor if

■ cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

**If pregnant or breast-feeding**, ask a health professional before use.

**Keep out of reach of children**. In case of overdose, get medical help or contact a Poison Control Center right away

### **Directions**

- take every 4 hours, or as directed by a doctor
- chew thoroughly before swallowing

adults and children 12 years of age and over	2 chewable tablets every 4 hours, not to exceed 12 chewable tablets in any 24-hour period
children 6 to under 12 years of age	1 chewable tablet every 4 hours, not to exceed 6 chewable tablets in any 24-hour period
children under 6 years of age	do not use

#### Other information

- each chewable tablet contains: potassium 5 mg and sodium 15 mg
- Store in a cool dry place at 20-25°C (68-77°F)

## **Inactive ingredients**

anhydrous citric acid, corn syrup, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin, malic acid, maltodextrin, pectin, potassium sodium tartrate, purified water, sodium chloride, trisodium citrate (anhydrous), sodium polymetaphosphate, sucralose, sucrose

Questions? 1-866-MUCINEX (1-866-682-4639)

### NDC 72854-085-16

Children's

Mucinex®

Cough Suppressant

**Antihistamine** 

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 m

Age 6+

Mixed Berry Flavor



## MUCINEX CHILDRENS MIGHTY CHEWS NIGHT TIME COLD AND FLU

acetaminophen, dextromethorphan hbr and doxylamine succinate tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72854-085
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg	
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	3.125 mg	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	162.5 mg	

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PECTIN (UNII: 89NA02M4RX)	
POTASSIUM SODIUM TARTRATE (UNII: QH257BPV3J)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALIC ACID (UNII: 817L1N4CKP)	
CORN SYRUP (UNII: 9G5L16BK6N)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ANHYDROUS TRISODIUM CITRATE (UNII: RS7A450LGA)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM POLYMETAPHOSPHATE (UNII: P1BM4ZH95L)	
SUCROSE (UNII: C151H8M554)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ETHYLCELLULOSE (UNII: 7Z8S9VYZ4B)	

Product Characteristics			
Color	purple	Score	no score
Shape	ROUND	Size	23mm
Flavor	BERRY (Mixed Berry)	Imprint Code	М
Contains			

Packaging				
#	Code		Marketing Start Date	Marketing End Date
1	NDC:72854- 085-16	16 in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	06/01/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/01/2025	

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

Revised: 1/2025 RB Health (US) LLC