

**MUCINEX CHILDRENS MIGHTY CHEWS COUGH NIGHTTIME- dextromethorphan hbr and doxylamine succinate tablet, chewable
RB Health (US) LLC**

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

Uses

- 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 72854-082-16

Children's
Mucinex®

Cough Suppressant

Antihistamine

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 m

Age 6+

Mixed Berry Flavor

**KEEP OUT OF REACH OF CHILDREN
USE UNDER ADULT SUPERVISION**

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



**MIGHTY CHEWS
COUGH
NIGHTTIME**

Dextromethorphan HBr 10 mg - Cough Suppressant
Doxylamine Succinate 6.25 mg - Antihistamine

✓ CONTROLS COUGH TO HELP YOU GET TO SLEEP
✓ EASY TO DOSE FORMAT

16 CHEWABLE TABLETS - MIXED BERRY FLAVOR

Drug Facts

Active ingredient (in each chewable tablet)

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

Purposes

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
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■ runny nose	■ sneezing
■ itching of the nose or throat	■ itchy, watery eyes

Tamper evident: Protected with a tamper evident seal. Do not use if seal under cap is broken or missing.

PEEL CORNER TO READ COMPLETE DRUG FACTS AND INFORMATION

<p>Drug Facts (Continued)</p> <p>Warnings</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ 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. <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ 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) <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> ■ taking sedatives or tranquilizers 	<p>Drug Facts (Continued)</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ 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 <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ 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. <p>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</p> <p>Directions</p> <ul style="list-style-type: none"> ■ take every 4 hours, or as directed by a doctor ■ chew thoroughly before swallowing 	<p>Drug Facts (Continued)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td>adults and children 12 years of age and over</td> <td>2 chewable tablets every 4 hours, not to exceed 12 chewable tablets in any 24-hour period</td> </tr> <tr> <td>children 6 to under 12 years of age</td> <td>1 chewable tablet every 4 hours, not to exceed 6 chewable tablets in any 24-hour period</td> </tr> <tr> <td>children under 6 years of age</td> <td>do not use</td> </tr> </table> <p>Other information</p> <ul style="list-style-type: none"> ■ each chewable tablet contains: potassium 5 mg and sodium 15 mg ■ Store in a cool dry place at 20-25°C (68-77°F) <p>Inactive ingredients</p> <p>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</p> <p>Questions? 1-866-MUCINEX (1-866-682-4639)</p>	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
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MUCINEX CHILDRENS MIGHTY CHEWS COUGH NIGHTTIME			
dextromethorphan hbr and doxylamine succinate tablet, chewable			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72854-082
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg	
Inactive Ingredients			
Ingredient Name	Strength		
FD&C RED NO. 40 (UNII: WZB9127XOA)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
PECTIN (UNII: 89NA02M4RX)			
POTASSIUM SODIUM TARTRATE (UNII: QH257BPV3J)			
WATER (UNII: 059QF0KO0R)			
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)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72854-082-16	16 in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	06/03/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/03/2024	

Labeler - RB Health (US) LLC (081049410)

Revised: 4/2024

RB Health (US) LLC