

**MUCINEX CHILDRENS MIGHTY CHEWS COUGH DAYTIME AND NIGHTTIME COMBO PACK- dextromethorphan hbr and doxylamine succinate
RB Health (US) LLC**

Mucinex Childrens Mighty Chews Cough Daytime and Nighttime Combo Pack

Drug Facts

Mucinex Children's Mighty Chews Cough Daytime:

Active ingredient (in each chewable tablet)

Dextromethorphan HBr 10 mg.

Mucinex Children's Mighty Chews Cough Nighttime:

Active ingredient (in each chewable tablet)

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Dextromethorphan HBr 10 mg.....Cough suppressant

Doxylamine succinate 6.25 mg.....Antihistamin

Uses

Mucinex Children's Mighty Chews Cough Daytime:

Uses temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold

Mucinex Children's Mighty Chews Cough Nighttime:

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

Mucinex Children's Mighty Chews Cough Daytime:

Warnings

Do not use 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
 - cough that occurs with too much phlegm (mucus)
 - persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- When using this product do not exceed recommended dosage

Stop use and ask a doctor if cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache. These could be signs of a serious condition.

Mucinex Children's Mighty Chews Cough Nighttime:

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
- marked drowsiness may occur
- excitability may occur, especially in children
- 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

Mucinex Children's Mighty Chews Cough Daytime+Mucinex Children's Mighty Chews Cough Nighttime::

- 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)

Mucinex Children's Mighty Chews Cough Daytime:

Inactive ingredients anhydrous citric acid, corn syrup, 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

Mucinex Children's Mighty Chews Cough Nighttime:

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 72854-083-32

DAY & NIGHT MIGHTY CHEWS COUGH

Mucinex® Children's

Dextromethorphan HBr - Cough Suppressant

Doxylamine succinate - Antihistamin

16 Chewable Tablets each

VALUE
PACK

Mucinex[®] Children's

6+
YRS

NDC 72854-083-32

MIGHTY CHEWS



DAYTIME



NIGHTTIME



See back panel for
actual tablet size

16 DAYTIME CHEWABLE TABLETS

TOTAL 32 CHEWABLE TABLETS • MIXED BERRY FLAVOR

16 NIGHTTIME CHEWABLE TABLETS

Nighttime	Mucinex Children's Mighty Chews Cough Nighttime	Mucinex Children's Mighty Chews Cough Daytime	Daytime																		
<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> excitability may occur, especially in children 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 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> <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 <table border="1"> <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 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>	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	<p>Drug Facts</p> <p>Active ingredient (in each chewable tablet)</p> <table border="1"> <tr> <td>Dextromethorphan HBr 10 mg</td> <td>Cough suppressant</td> </tr> <tr> <td>Doxylamine succinate 6.25 mg</td> <td>Antihistamin</td> </tr> </table> <p>Uses</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> runny nose itching of the nose or throat sneezing itchy, watery eyes <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 taking sedatives or tranquilizers</p> <p>When using this product</p> <ul style="list-style-type: none"> do not exceed recommended dosage marked drowsiness may occur 	Dextromethorphan HBr 10 mg	Cough suppressant	Doxylamine succinate 6.25 mg	Antihistamin	<p>Drug Facts</p> <p>Active ingredient (in each chewable tablet)</p> <table border="1"> <tr> <td>Dextromethorphan HBr 10 mg</td> <td>Cough suppressant</td> </tr> </table> <p>Uses temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold</p> <p>Warnings</p> <p>Do not use 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> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> a sodium-restricted diet cough that occurs with too much phlegm (mucus) persistent or chronic cough such as occurs with smoking, asthma, or emphysema <p>When using this product do not exceed recommended dosage</p> <p>Stop use and ask a doctor if cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache. 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ALWAYS WAIT AT LEAST 4 HOURS BEFORE GIVING ANOTHER DOSE OF EITHER MUCINEX MIGHTY CHEWS. USE AS DIRECTED.</p> <p>PARENTS: Learn about teen medication abuse. www.StopMedicineAbuse.org</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">No varnish</p>
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MUCINEX CHILDRENS MIGHTY CHEWS COUGH DAYTIME AND NIGHTTIME COMBO PACK

dextromethorphan hbr and doxylamine succinate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72854-083
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72854-083-32	1 in 1 CARTON	06/03/2024	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	16
Part 2	1 BOTTLE	16

Part 1 of 2

MUCINEX CHILDRENS MIGHTY CHEWS COUGH

dextromethorphan hydrobromide tablet, chewable

Product Information

Item Code (Source)	NDC:72854-081
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Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: QD3BT10KXU)	DEXTROMETHORPHAN	

DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9DZRT19KTH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
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Inactive Ingredients

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

Product Characteristics

Color	red	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:72854-081-16	16 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	06/03/2024	

Part 2 of 2

MUCINEX CHILDRENS MIGHTY CHEWS COUGH NIGHTTIME

dextromethorphan hbr and doxylamine succinate tablet, chewable

Product Information

Item Code (Source)	NDC:72854-082
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

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

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)		

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

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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: 11/2024

RB Health (US) LLC