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

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**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

■ exciteability may ocur, especial in chidren
■ 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

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**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®Childrens
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

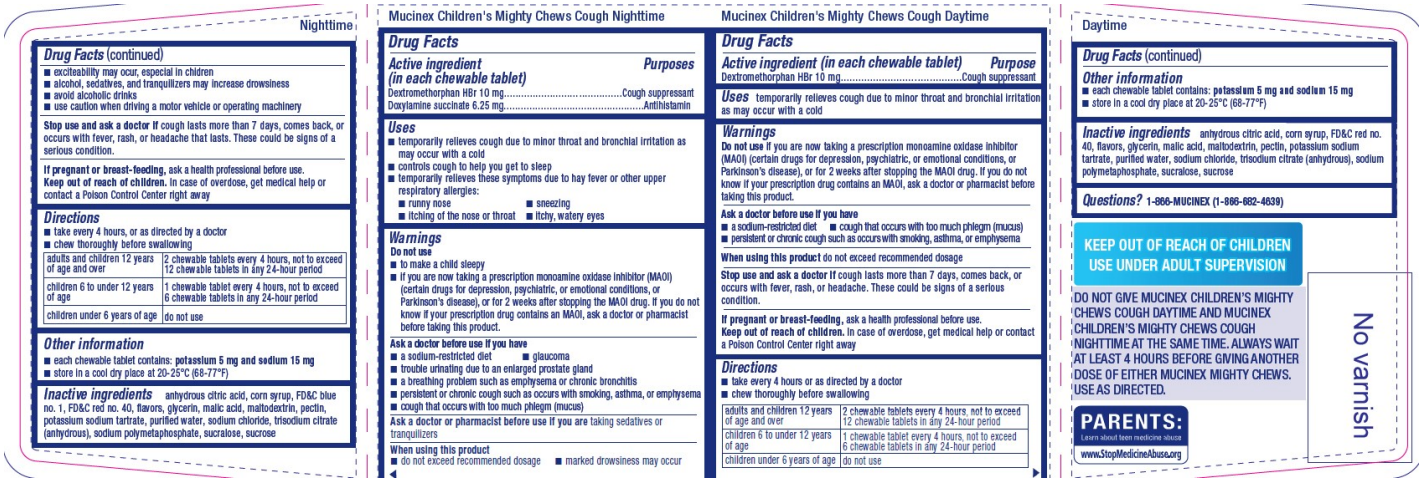

16 DAYTIME CHEWABLE TABLETS

## NIGHTTIME


See back panel for actual tablet size

16 NIGHTTIME CHEWABLE TABLETS

TOTAL 32 CHEWABLE TABLETS · MIXED BERRY FLAVOR




# 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 |

## 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 |
| **Route of Administration** | ORAL |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) | DEXTROMETHORPHAN | |

| | | |
|---|---|---|
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |

## 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** | 234mm |
| **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 | |

## 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