MUCINEX CHILDRENS MIGHTY CHEWS NIGHT TIME COLD AND FLU- acetaminophen, dextromethorphan hbr and doxylamine succinate tablet, chewable
RB Health (US) LLC

Mucinex Children's Mighty Chews Cough Nighttime

Drug Facts

Acetaminophen 162.5 mg

Dextromethorphan HBr 5 mg

Doxylamine succinate 3.125 mg

Acetaminophen 162.5 mg.....Pain reliever/fever reducer

Dextromethorphan HBr 5 mg..... .....Cough suppressant
Doxylamine succinate 3.125 mg.....Antihistamine

Uses

■ temporarily relieves these common cold and flu symptoms:

■ minor aches and pains

■ sore throat

■ headache
■ cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
■ runny nose

■ sneezing
■ temporarily reduces fever
■ controls cough to help the user get to sleep

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if:
■ adult takes more than 6 doses (24 chewable tablets) in 24 hours, which is the maximum daily amount
■ child takes more than 5 doses (10 chewable tablets) in 24 hours, which is the maximum daily amount
■ taken with other drugs containing acetaminophen
■ adult has 3 or more alcoholic drinks every day while using this product

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

■ to make a child sleepy
■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
■ if the user is 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

■ has liver disease
■ has a sodium-restricted diet
■ has glaucoma
■ has a breathing problem such as emphysema or chronic bronchitis
■ has difficulty in urination due to enlargement of the prostate gland
■ is a child with pain of arthritis

Ask a doctor or pharmacist before use if you are

■ taking the blood thinning drug warfarin
■ taking sedatives or tranquilizers

When using this product

■ do not use more than directed (see Overdose warning)
■ excitability may occur, especially in children
■ marked drowsiness may occur
■ alcohol, sedatives, and tranquilizers may increase the drowsiness effect
■ avoid alcoholic beverages
■ use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

■ pain or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
■ 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.

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

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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not take more than directed (see Overdose warning)
- chew thoroughly before swallowing
- dose every 4 hours or as directed by a doctor

adults and children 12 years of age and over	4 chewable tablets every 4 hours, not to exceed 6 doses (24 chewable tablets) in any 24-hour period
children 6 to under 12 years of age	2 chewable tablets every 4 hours, not to exceed 5 doses (10 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 13 mg
- Store in a cool dry place at 20-25°C (68-77°F)

Inactive ingredients

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

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

NDC 72854-085-16

Children's
Mucinex®

Cough Suppressant

Antihistamine

Acetaminophen 162.5 mg

Dextromethorphan HBr 5 mg

Doxylamine succinate 3.125 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
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	3.125 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	162.5 mg

Inactive Ingredients

Ingredient Name	Strength
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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PECTIN (UNII: 89NA02M4RX)	
POTASSIUM SODIUM TARTRATE (UNII: QH257BPV3J)	
WATER (UNII: 059QF0KO0R)	
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:72854-085-16	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: 11/2025

RB Health (US) LLC