MUCINEX CHILDRENS FREEFROM MULTI-SYMPTOM COLD, FLU AND SORE THROAT AND MUCINEX CHILDRENS FREEFROM MULTI-SYMPTOM COLD AND FLU NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, and triprolidine hydrochloride RB Health (US) LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Mucinex® Children's FreeFrom Multi-Symptom Cold, Flu & Sore Throat and Mucinex® Children's FreeFrom Multi-Symptom Cold & Flu Nighttime

DAYTIME MULTI-SYMPTOM COLD, FLU & SORE THROAT - Ages 6+ YRS.

Drug Facts

Active ingredients (in each 10 mL)	Purposes
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
 - cough
 - nasal congestion
 - minor aches and pains
 - sore throat
 - headache
 - stuffy nose
 - sinus congestion and pressure
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if your child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

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

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if the child has

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if the child is taking the blood thinning drug warfarin

When using this product do not use more than directed (see Overdose warning)

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

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. Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions

- this product does not contain directions or complete warnings for adult use
- do not give more than directed (see Overdose warning)
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- children 6 to under 12 years of age: 10 mL in dosing cup provided every 4 hours while symptoms last; do not give more than 5 doses in any 24-hour period
- children under 6 years of age: do not use

Other information

- each 10 mL contains: **sodium 6 mg**
- store at 20-25°C (68-77°F)
- do not refrigerate

Inactive ingredients

ammonium glycyrrhizate, anhydrous citric acid, cochineal carmine, edetate disodium, flavors, glycerin (soy), maltodextrin, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions?

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

MULTI-SYMPTOM COLD & FLU NIGHTTIME - Ages 6+ YRS.

Drug Facts

Active ingredients (in each 10 mL)	Purposes
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg Triprolidine HCl 1.25 mg	Nasal decongestant Antihistamine

- temporarily relieves these common cold and flu symptoms:
 - minor aches and pains
 - headache
 - sore throat
 - nasal congestion
 - runny nose
 - sneezing
 - cough
 - stuffy nose
- temporarily reduces fever
- controls cough to help your child get to sleep

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if your child takes:

- more than 1625 mg in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

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

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- to make a child sleepy
- in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if the child has

- liver disease
- heart disease
- diabetes

- high blood pressure
- thyroid disease
- glaucoma
- a breathing problem such as chronic bronchitis
- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if the child is

- 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
- may cause marked drowsiness
- sedatives and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

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. Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions

- this product does not contain directions or complete warnings for adult use
- do not give more than directed (see Overdose warning)
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- children 6 to under 12 years of age: 10 mL in dosing cup provided every 4 hours while symptoms last; do not give more than 4 doses in any 24-hour period
- children under 6 years of age: do not use

Other information

• each 10 mL contains: **sodium 6 mg**

- store at 20-25°C (68-77°F)
- do not refrigerate

Inactive ingredients

ammonium glycyrrhizate, anhydrous citric acid, cochineal carmine, edetate disodium, flavors, glycerin (soy), maltodextrin, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions?

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

Dist. by: RB Health (US) Parsippany, NJ 07054-0224 Made in Mexico

PRINCIPAL DISPLAY PANEL - Kit Carton

Pediatrician Recommended [†] NDC 63824-945-34

TRIPLE PACK INCLUDES:

2X DAYTIME 1X NIGHTTIME

Mucinex® Children's

FREEFROM

MULTI-SYMPTOM COLD, FLU & SORE THROAT

ACETAMINOPHEN – PAIN RELIEVER/FEVER REDUCER DEXTROMETHORPHAN HBr – COUGH SUPPRESSANT GUAIFENESIN – EXPECTORANT PHENYLEPHRINE HCI – NASAL DECONGESTANT

MULTI-SYMPTOM COLD & FLU NIGHTTIME

ACETAMINOPHEN – PAIN RELIEVER/FEVER REDUCER DEXTROMETHORPHAN HBr – COUGH SUPPRESSANT PHENYLEPHRINE HCI – NASAL DECONGESTANT TRIPROLIDINE HCI – ANTIHISTAMINE

FREEFROM ARTIFICIAL FLAVORS, COLORS & DYES • ALCOHOL & SUGAR

ELDERBERRY

& CHERRY NATURAL FLAVOR

AGES 6+ YRS.

THREE - 4 FL OZ (118 mL) bottles TOTAL - 12 FL OZ (354 mL)





MUCINEX CHILDRENS FREEFROM MULTI-SYMPTOM COLD, FLU AND SORE THROAT AND MUCINEX CHILDRENS FREEFROM MULTI-SYMPTOM COLD AND FLU NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, and triprolidine hydrochloride kit

Produ	Product Information					
Produ	ct Type	HUMAN OTC DRUG	Item Code (Source) NDC:63824-945			
Packa	aging					
# It	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:	63824-945-34	1 in 1 CARTON	08/01/2020			
-						
Quantity of Parts						
Part #	Pa	ckage Quantity	Total Produ	ct Quantity		
Part 1	2 BOTTLE		236 mL			

Part 1	2 BOTTLE	236 mL
Part 2	1 BOTTLE	118 mL

Part 1 of 2

MUCINEX CHILDRENS FREEFROM MULTI-SYMPTOM COLD, FLU AND SORE THROAT

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

Product II	nformation					
Route of Ad	ministration	ORAL				
Active Ing	redient/Active	Moiety				
	Ingre	dient Name		Basis of Stre	ength Stren	ngt
ACETAMINOP	HEN (UNII: 3620917	L9D) (ACETAMINOPH	HEN - UNII:36209	ITL9D) ACETAMINOPHEN	325 mg in 10 r	
	IORPHAN HYDROI ORPHAN - UNII:7355	BROMIDE (UNII: 9D2 X3ROTS)	2RTI9KYH)	DEXTROMETHORPI HYDROBROMIDE	HAN 10 mg in 10 r	mL
GUAIFENESIN	I (UNII: 495W7451V0	Q) (GUAIFENES IN - U	NII:495W7451VQ)	GUAIFENESIN	200 mg in 10 m	
PHENYLEPHR UNII:1WS297W		RIDE (UNII: 04JA59TN	NSJ) (PHENYLEPHI	RINE - PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 r	nL
Inactive Ir	gredients					
		Ingredient N	ame		Strength	1
AMMONIUM (GLYCYRRHIZATE (U	JNII: 3VRD35U26C)				
ANHYDROUS	CITRIC ACID (UNII:	XF417D3PSL)				
CARMINIC AC	ID (UNII: CID8Z8N9	5N)				
EDETATE DIS	ODIUM (UNII: 7FLD	91C86K)				
MALTODEXT	RIN (UNII: 7CVR7L4A	2D)				
PROPYLENE	GLYCOL (UNII: 6DC	9Q167V3)				
WATER (UNII:	059QF0KO0R)					
SODIUM BEN	ZOATE (UNII: OJ245	SFE5EU)				
SORBITOL (U	NII: 506T60A25R)					
SUCRALOSE	UNII: 96K6UQ3ZD4)				
XANTHAN GU	M (UNII: TTV12P4NE	EE)				
Product C	haracteristics					
Color		red	Score			
Shape			Size			
Flavor		BERRY	Imprint Co	ode		
Contains						
Packaging	l					
# Item Code	Pac	kage Description	on	Marketing Start Date	Marketing E Date	nd
1	1 in 1 CARTON					
1	118 mL in 1 BOTT Package	LE; Type 1: Conveni	ience Kit of Co-			

Marketing
CategoryApplication Number or Monograph
CitationMarketing Start
DateMarketing End
Date

Part 2 of 2

MUCINEX CHILDRENS FREEFROM MULTI-SYMPTOM COLD AND FLU NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and triprolidine hydrochloride solution

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg in 10 mL		
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL		
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	1.25 mg in 10 mL		

Inactive Ingredients

Ingredient Name	Strength
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARMINIC ACID (UNII: CID8Z8N95N)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics				
Color	red	Score		
Shape		Size		
Flavor	BERRY	Imprint Code		
Contains				

Pa	ckaging					
#	ltem Code	P	ackage Description	Marketing Start Date	Marketing End Date	
1	1 i	n 1 CARTON				
1		8 mL in 1 BC ckage	DTTLE; Type 1: Convenience Kit of Co-			
Marketing Information						
Marketing CategoryApplication Number or MonographMarketing StartMarketing ECategoryCitationDateDate						
отс	C monograph f	nal part341		08/01/2020		
Marketing Information						
	arketing			00/01/2020		
	arketing ^{Marketing} Category	Inform			Marketing End Date	

Labeler - RB Health (US) LLC (081049410)

Establishment

Name	Address	ID/FEI	Business Operations
RB Salute Mexico, S.A. de C.V.		812814950	manufacture(63824-945)

Revised: 1/2023

RB Health (US) LLC