MUCINEX FAST MAX LIQUID COLD AND FLU KICKSTART AND MUCINEX NIGHTSHIFT KICKSTART- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hci, triprolidine hci 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 Fast-Max Kickstart Severe Cold & Flu and Night Time Cold & Flu

Drug Facts

KICKSTART SEVERE COLD & FLU:

Acetaminophen 650mg	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg	Cough suppressant
Guaifenesin 400 mg	
Phenylephrine HCI 10mg	

NIGHT TIME SEVERE COLD & FLU:

Acetaminophen 650mg	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg	
Phenylephrine HCl 10mg	
Triprolidine HCl 2.5 mg	

Uses

KICKSTART SEVERE COLD & FLU:

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

NIGHT TIME SEVERE COLD & FLU:

temporarily relieves these common cold and flu symptoms:

- cough
- nasal congestion

- minor aches and pains
- sore throat
- headache
- sinus congestion and pressure
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes due to hay fever
- temporarily reduces fever
- controls cough to help you get to sleep

Warnings

KICKSTART SEVERE COLD & FLU:

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 6 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily 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

■ 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 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

liver disease

■ heart disease

diabetes

■ high blood pressure

thyroid disease

■ trouble urinating due to an enlarged prostate gland

persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis,

- or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

When using this product do not use more than directed

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 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.

NIGHT TIME SEVERE COLD & FLU:

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily 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

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 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

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- 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 the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- do not use more than directed
- 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

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 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.

Directions

KICKSTART SEVERE COLD & FLU

■ do not take more than directed (see Overdose warning)

■ do not take more than 6 doses in any 24-hour period

measure only with dosing cup provided

■ do not use dosing cup with other products

dose as follows or as directed by a doctor
 adults and children 12 years of age and

over: 20 mL in dosing cup provided every 4 hours

children under 12 years of age: do not use

NIGHT TIME SEVERE COLD & FLU

■ do not take more than directed (see Overdose warning)

■ do not take more than 4 doses in any 24-hour period

measure only with dosing cup provided

do not use dosing cup with other products

■ dose as follows or as directed by a doctor

■ adults and children 12 years of age and over: 20 mL in dosing cup provided every 4 hours

children under 12 years of age: do not use

Other Information

KICKSTART SEVERE COLD & FLU

each 20 mL contains: sodium 12 mg

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

NIGHT TIME SEVERE COLD & FLU

each 20 mL contains: sodium 16 mg

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

KICKSTART SEVERE COLD & FLU

ammonium glycyrrhizate, anhydrous citric acid, D&C yellow no. 10, edetate disodium, FD&C blue no. 1, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

NIGHT TIME SEVERE COLD & FLU

ammonium glycyrrhizate, anhydrous citric acid, ascorbic acid, edetate disodium, FD&C blue no. 1,

FD&C red no. 40, flavors, glycerin (soy), propylene glycol, sodium benzoate, sorbitol, sucralose, triacetin, triethyl citrate, water, xanthan gum

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

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.**

Purposes

KICKSTART SEVERE COLD & FLU:

Dextromethorphan HBr 20 mg	Cough suppressant
Guaifenesin 400 mg	Expectorant
Phenylephrine HCI 10mg	Nasal decongestant

NIGHT TIME SEVERE COLD & FLU:

Dextromethorphan HBr 20 mg	Cough suppressant
Phenylephrine HCl 10mg	
Triprolidine HCl 2.5 mg	Antihistamine

NDC 72854-139

MUCINEX FAST-MAX Kickstart + Nighttime Cold & Flu Pack

Kickstart Severe Cold & Flu:

Acetaminophen – Pain Reliever/Fever Reducer Dextromethorphan HBr – Cough Suppressant Guaifenesin – Expectorant • Phenylephrine HCl – Nasal Decongestant

Nighttime Severe Cold & Flu:

Acetaminophen – Pain Reliever/Fever Reducer Dextromethorphan HBr – Cough Suppressant Phenylephrine HCl – Nasal Decongestant • Triprolidine HCl – Antihistamine

FOR AGES 12+ TWO - 6 FL OZ (180 mL) bottles

TOTAL – 12 FL OZ (360 mL)



NIGHT TIME SEVERE COLD & FLU

Tamper evident: Do not use if neckband on bottle cap is broken or missing.

KICKSTART SEVERE COLD & FLU

Drug Facts Active ingredients (in each 20 mL) Purposes Acetaminophen 650 mg Pain reliever/fever reducer Dextromethorphan HBr 20 mg Cough suppressant Phenylephrine HCI 10 mg Nasal decongestant Triprolidine HCI 2.5 mg Antihistamine Uses • temporarily relieves these common cold and flu symptoms: • cough nasal congestion • headache sinus congestion and pressure • itching of the nose or throat itchy, watery eyes due to hay fever • temporarily reduces fever controls cough to help you get to sleep	Drug Facts Active Ingredients (in each 20 mL) Purposes Acetaminophen 650 mg
 Warnings Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take: more than 4,000 mg in 24 hours, which is the maximum daily amount with other drugs containing acetaminophen 3 or more alcoholic drinks daily while using this product Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: I skin reddening I blisters I ash If a skin readtion 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. 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. 	Warnings Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take: ■ more than 6 doses in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen 3 or more alcoholic drinks daily while using this product Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: # skin reaction occurs, stop use and seek medical help right away. Sore throat warning: If 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. ■ 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
Ask a doctor before use if you have liver disease heart disease diabetes high blood pressure thyroid disease glaucoma trouble urinating due to an enlarged prostate gland a breathing problem such as emphysema or chronic bronchitis glaucoma 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 the blood thinning drug warfarin taking sedatives or tranquilizers When using this product d onot use more than directed	Ask a doctor before use if you have diabetes high blood pressure trouble urinating due to an enlarged prostate gland persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema cough that occurs with too much phlegm (mucus) Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin When using this product do not use more than directed Stoo use and ask a doctor if
 excitability may occur, especially in children 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 nervousness, dizziness, or sleeplessness occur pain, nasal congestion, or cough gets worse or lasts more than 7 days fever gets worse or lasts more than 3 days 	 Stop use and ask a doctor if nervousness, dizziness, or sleeplessness occur pain, nasal congestion, or cough gets worse or lasts more than 7 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. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.





MUCINEX FAST MAX LIQUID COLD AND FLU KICKSTART AND MUCINEX NIGHTSHIFT KICKSTART

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hci, triprolidine hci kit

Pr	Product Information								
Product Type HUMAN OTC DRUG Item Code (Source) NDC:72854-139									
Pa	ackaging								
#	Item Code	Package Description	Marketing Start Date	Marketing End Date					
1	NDC:72854-139-26	1 in 1 CARTON	05/01/2023						
_									
Qı	uantity of Parts								

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	180 mL
Part 2	1 BOTTLE	180 mL

Part 1 of 2

MUCINEX FAST-MAX KICKSTART SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

Product Information

ltem Code (Source)	NDC:72854-138
Route of Administration	ORAL

Active Ingredient/Active Moiety						
Ingredient Name	Basis of Strength	Strength				
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL				
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL				
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 20 mL				
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL				

Inactive Ingredients

	Ingradient N	lamo	Strength				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)							
FD&C BLUE NO. 1 (UNII: H3R47)	(3TBD)						
SODIUM CITRATE, UNSPECIFIE	D FORM (UNII: 1Q73	BQ2JULR)					
SORBITOL (UNII: 506T60A25R)							
SUCRALOSE (UNII: 96K6UQ3ZD4)						
XANTHAN GUM (UNII: TTV12P4N	EE)						
GLYCERIN (UNII: PDC6A3C0OX)							
PROPYLENE GLYCOL (UNII: 6DC	9Q167V3)						
SODIUM BENZOATE (UNII: OJ24	5FE5EU)						
WATER (UNII: 059QF0K00R)							
ANHYDROUS CITRIC ACID (UNII	: XF417D3PSL)						
EDETATE DISODIUM (UNII: 7FLC	91C86K)						
PROPYL GALLATE (UNII: 8D4SNM	17V92)						
Product Characteristics	5						
Color	green	Score					
Shape		Size					

	vor		Iv.	IENTHOL		Imprint	Code			
Con	ntains					-				
-										
Ра	ckaging 								•	
#	ltem Code			Package De	scriptio	n		Market Start D		Marketing End Date
	IDC:72854- 38-66			E; Type 9: Other /Device/Biologica		art 3 Comi	pination			
Ma	arketin	ng In	format	ion						
	Marketin Categor		Applica	tion Number o Citation		graph		ng Start te	Mar	keting End Date
отс	monograp	h final	part341				05/01/2023			
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				ME SEVER						
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hyd	Irochlorid	e solu	tion							
hyc	Irochlorid	e solu	tion							
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Pro		form	ation	NDC:72854-140						
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Pro Iter Rou Act	oduct In m Code (S ute of Adu tive Ingr tive Ingr	form Source minist redier ORPHA DRPHAN NE HYI	ation ation ration ht/Active Ingree N HYDROB - UNII:7355X	ORAL Moiety dient Name ROMIDE (UNII: 90			DEXTR HYDRO	OMETHORPH	-	20 mg
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SODIUM BENZOATE	(UNII: OJ245FE	5EU)					
SORBITOL (UNII: 506	T60A25R)						
WATER (UNII: 059QF0	KO0R)						
XANTHAN GUM (UNII:	TTV12P4NEE)						
ASCORBIC ACID (UNI	I: PQ6CK8PD0	R)					
EDETATE DISODIUM	(UNII: 7FLD91	С86К)					
PROPYLENE GLYCOL	UNII: 6DC9Q	167V3)					
SUCRALOSE (UNII: 96	K6UQ3ZD4)						
TRIACETIN (UNII: XHX	3C3X673)						
Product Charac	teristics						
Color		blue	Score				
Shape			Size				
Flavor		FRUIT	Imprint Code				
Contains							
Packaging							
# Item Code		Package Desci	ription		Marketi Start Da		rketing d Date
1 NDC:72854- 140-66 Produc				ination			
140-66 Produc	ct (e.g., Drug/L	Device/Biological Pro	Dauct)				
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OTC monograph final	part341		()5/01/2023			
Marketing In	formati	on					
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Labeler - RB Health (US) LLC (081049410)

Revised: 6/2023

RB Health (US) LLC