

MAXIMUM STRENGTH SEVERE CONGESTION RELIEF- acetaminophen, guaifenesin, dextromethorphan hydrobromide, and phenylephrine hydrochloride capsule, liquid filled Walgreens

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.

Maximum Strength Severe Congestion Relief

Drug Facts

Active ingredients (in each softgel)	Purpose
Acetaminophen 325 mg	Pain reliever
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves common cold/flu symptoms:
- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- minor aches & pains
- headache
- fever
- sore throat
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- 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 you take

- more than 12 softgels in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 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.

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
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

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

- you get nervous, dizzy or sleepless
- 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 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 directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- take only as directed - see **Overdose warning**
- do not exceed 4 doses per 24 hours

adults & children 12 years & over	2 softgels with water every 4 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

- **when using other Nighttime or Daytime products, carefully read each label to ensure correct dosing**

Other information

- store between 20-25 °C
- avoid excessive heat

Inactive ingredients

FD&C Red #40, FD&C Yellow # 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

Questions or comments?

Call toll free: 1-888-333-9792

PRINCIPAL DISPLAY PANEL

Walgreens Maximum Strength Severe Congestion Relief

Compare to MUCINEX® SINUS-MAX® Severe

Congestion Relief active ingredients††

ACETAMINOPHEN/PAIN RELIEVER

DEXTROMETHORPHAN HBr/ COUGH SUPPRESSANT

GUAIFENESIN/ EXPECTORANT

PHENYLEPHRINE HCL/NASAL DECONGESTANT

DISSOLVES QUICKLY

MAXIMUM STRENGTH

Relieves Sinus Congestion, Thins and Loosens Mucus, Relieves Headache, Controls Cough

16

SOFTGELS

Walgreens

Drug Facts

Active Ingredients (In each softgel) **Purposes**

- Acetaminophen 325 mg.....Pain reliever
- Dextromethorphan HBr 10 mg.....Cough suppressant
- Guaifenesin 200 mg.....Expectorant
- Phenylephrine HCl 5 mg.....Nasal decongestant

Uses

- temporarily relieves: nasal congestion; headache; minor aches and pains; sinus congestion and pressure; cough
- temporarily promotes nasal and/or sinus drainage; helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageway of bothersome mucus and make coughs more productive.

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 12 softgels in 24 hours, which is the maximum daily amount.

With other drugs: Do not use acetaminophen with other drugs containing acetaminophen or 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.

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, psychoses, Parkinson's disease, or帕金森'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 enlarged prostate gland; glaucoma; shallow breathing due to 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, 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. If 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 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 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)
- do not take more than 12 softgels in any 24-hour period
- adults and children 12 years of age and older: take 2 softgels every 4 hours
- children under 12 years of age: do not use

Other Information

- store between 20°C to 25°C (68°F to 77°F)
- avoid excessive heat

Inactive Ingredients

FD&C yellow #6, gelatin, glycerin, polyethylene glycol, potassium, propylene glycol, purified water, sorbitol solution, titanium dioxide

Questions or comments? 1-888-333-8792

Walgreens Pharmacist Survey
This product is not manufactured or distributed by RB Health LLC, owner of the registered trademark Mucinex® SINUS-MAX®.
TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

LOT:
EXP:

Barcode: ITEM 748436
3 11917 21495 5

Recyclable
PAPER MULTILAYER TRAY

Drug Facts (continued)

Ask a doctor before use if you have:

- liver disease; heart disease; diabetes; high blood pressure; thyroid disease; trouble urinating due to enlarged prostate gland; glaucoma; shallow breathing due to 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
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- fever gets worse or lasts more than 3 days
- redness or swelling is present. If 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.

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Walgreens
RECOMMENDED
Health expertise you rely on™

Walgreens

Compare to Maximum Strength Mucinex® SINUS-MAX® Severe Congestion Relief active ingredients!

NDC 0363-5554-16

NEW

Severe Congestion Relief

ACETAMINOPHEN 325 mg / PAIN RELIEVER
DEXTROMETHORPHAN HBr 10 mg / COUGH SUPPRESSANT
GUIAFENESIN 200 mg / EXPECTORANT
PHENYLEPHRINE HCl 5 mg / NASAL DECONGESTANT

MAXIMUM STRENGTH

- Relieves headache, sinus pressure & congestion
- Thins & loosens mucus
- Controls cough
- 12 years & older

16 SOFTGELS*
(*LIQUID-FILLED CAPSULES)

ACTUAL SIZE

MAXIMUM STRENGTH SEVERE CONGESTION RELIEF

acetaminophen, guaifenesin, dextromethorphan hydrobromide, and phenylephrine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-5554
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
GUIAFENESIN (UNII: 495W7451VQ) (GUIAFENESIN - UNII:495W7451VQ)	GUIAFENESIN	200 mg
DEXTRORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTRORPHAN - UNII:7355X3ROTS)	DEXTRORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	Score	no score
Shape	OVAL (OBLONG)	Size	20mm
Flavor		Imprint Code	341
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-5554-16	2 in 1 CARTON	02/04/2020	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/04/2020	

Labeler - Walgreens (008965063)

Registrant - Spirit Pharmaceuticals LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
MEDGEL PVT LTD		677385498	manufacture(0363-5554)

Revised: 4/2020

Walgreens