MAXIMUM STRENGTH SINUS RELIEF- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, doxylamine succinate
Topco Associates LLC

MAXIMUM STRENGTH Sinus Relief

MAXIMUM STRENGTH Sinus Relief Day**

Drug Facts

Active ingredients (in each softgel) DAY

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Purposes

Pain reliever
Cough suppressant
Expectorant
Nasal decongestant

Uses

• temporarily relieves:
• nasal congestion • headache • cough • minor aches & pains • sinus congestion & pressure
• temporarily 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
• with other drugs containing acetaminophen
• 3 or more alcoholic drinks every day while using these 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 • diabetes • high blood pressure • thyroid disease • trouble urinating due to 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 these products • 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 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: In case of overdose, get medical help or contact a Poison Control Center right away.

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 at 20-25°C (68-77°F)
• protect from light, heat and moisture

Inactive ingredients

edible printing ink, FD&C Blue no. 1, FD&C Red no. 40, gelatin, glycerin, polyethylene glycol 400, povidone K30, propylene glycol, purified water, sorbitol sorbitan solution

Questions or comments?

Call: **1-888-423-0139**

MAXIMUM STRENGTH Sinus Relief Night**

Drug Facts

Active ingredients (in each softgel) NIGHT

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Doxylamine succinate 6.25 mg
Phenylephrine HCl 5 mg

Purposes

Pain reliever
Cough suppressant
Antihistamine
Nasal decongestant

Uses

• temporarily relieves:
• nasal congestion • headache • cough • minor aches & pains • sinus congestion & pressure • runny nose and sneezing
• temporarily promotes nasal and/or sinus drainage

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 containing acetaminophen
• 3 or more alcoholic drinks every day while using these products

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 • diabetes • high blood pressure • thyroid disease •

trouble urinating due to enlarged prostate gland • glaucoma • a breathing problem such as emphysema or chronic bronchitis • 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 • taking sedatives or tranquilizers

When using these products
• **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
• be careful 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 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: In case of overdose, get medical help or contact a Poison Control Center right away.

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 at 20-25°C (68-77°F)
• protect from light, heat and moisture

Inactive ingredients

edible printing ink, FD&C Blue no. 1, gelatin, glycerin, polyethylene glycol 400, povidone K30, propylene glycol, purified water, sorbitol sorbitan solution

Questions or comments?

Call: **1-888-423-0139**

COMPARE TO MUCINEX® SINUS-MAX® DAY ACTIVE INGREDIENTS*

COMPARE TO MUCINEX® SINUS-MAX® NIGHT ACTIVE INGREDIENTS*

DAY TIME FOR AGES 12+
NIGHT TIME FOR AGES 12+

*These products are not manufactured or distributed by Reckitt Benckiser, distributor of Mucinex® Sinus-Max® Day & Night Softgel

**Per 4-hour dose.

Do not take DAY & NIGHT softgels at the same time. Do not take more than a total of 12 softgels in a 24-hour period. Do not take the first dose of the NIGHT softgels sooner than 4 hours after the last dose of the DAY softgels unless directed by a doctor.

Take only as directed.

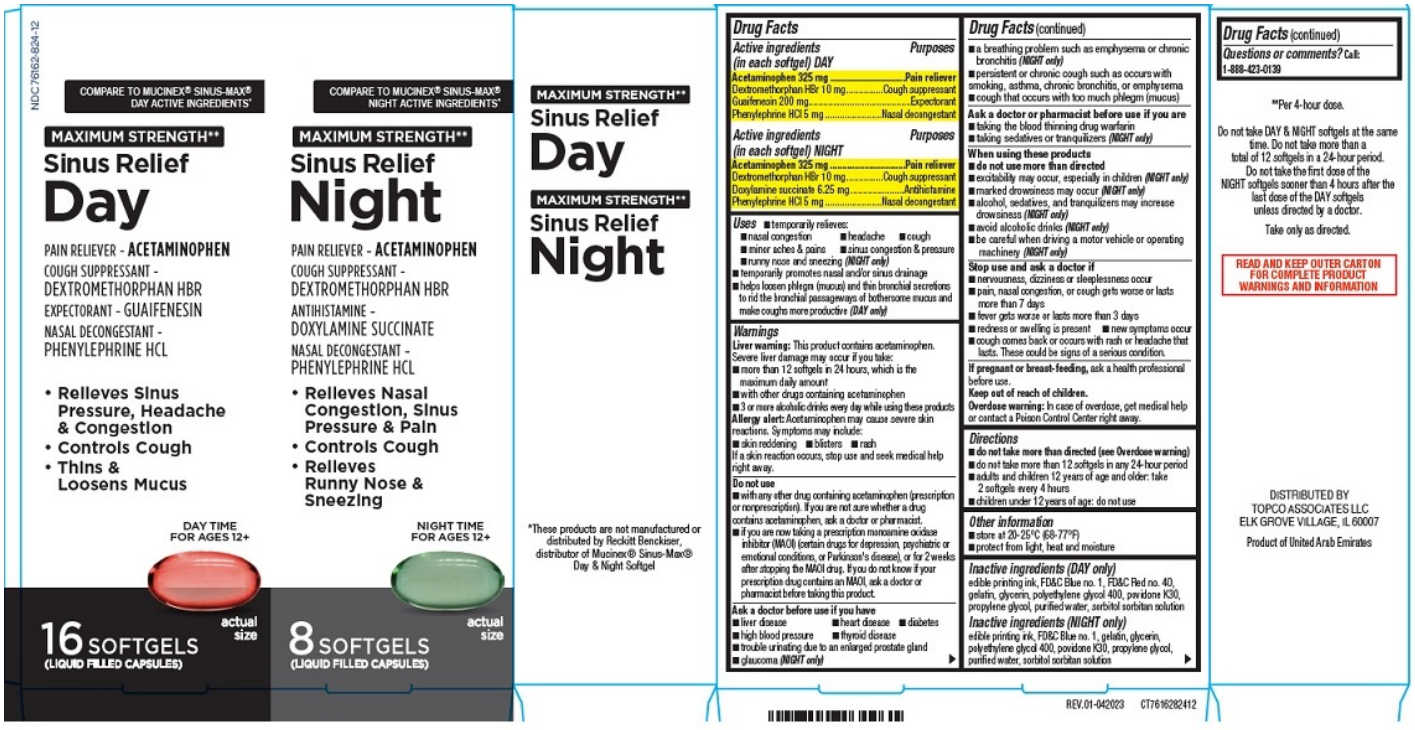
READ AND KEEP OUTER CARTON FOR COMPLETE PRODUCT WARNINGS AND INFORMATION

DISTRIBUTED BY
TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007

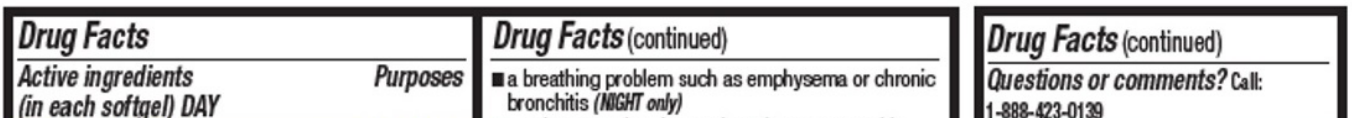
Product of United Arab Emirates

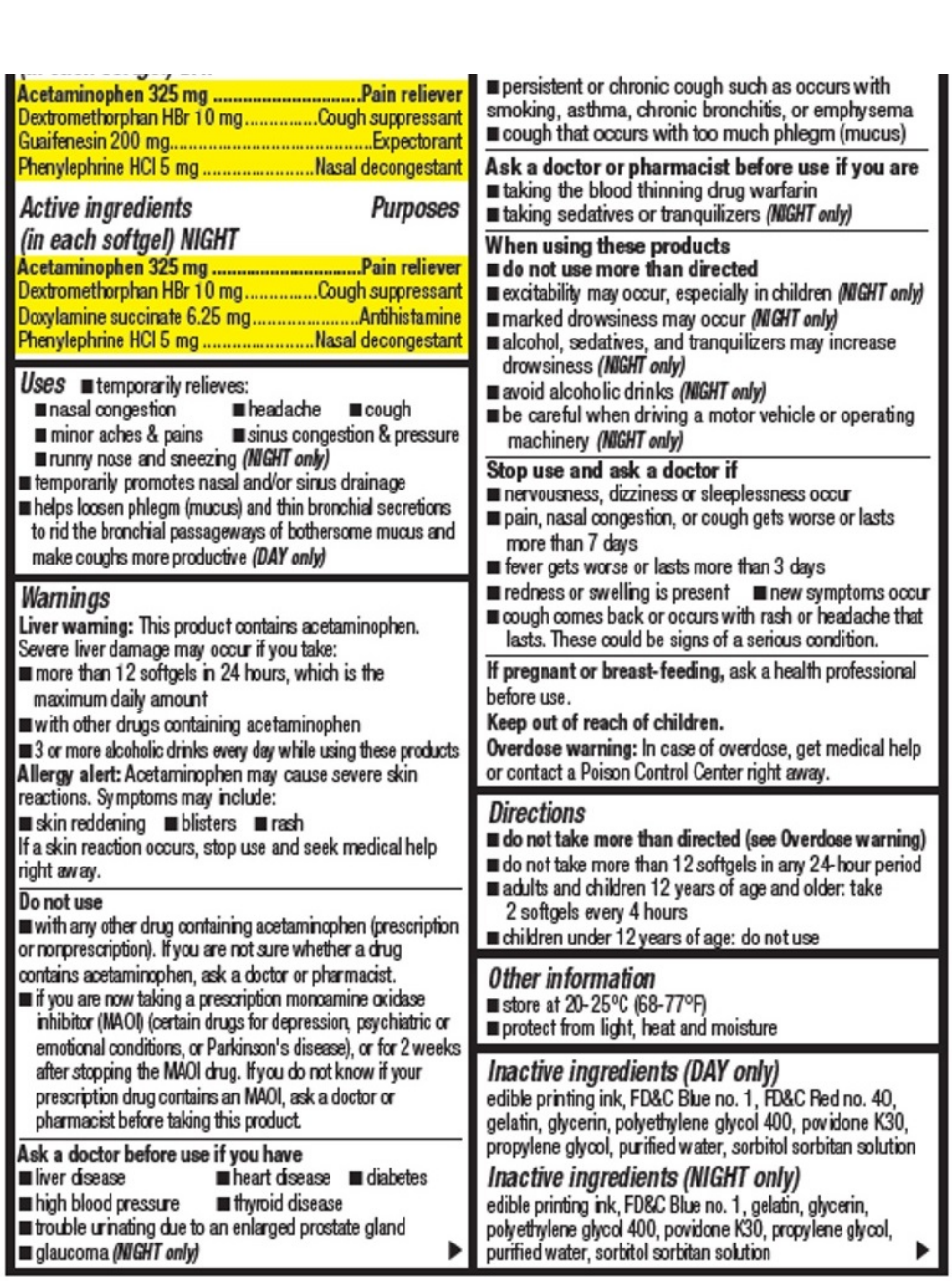
REV.01-042023 CT7616282412

Packaging



DRUG FACTS TABLE





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

Active ingredients (in each softgel) NIGHT — **Purposes**

Acetaminophen 325 mg ..... Pain reliever
Dextromethorphan HBr 10 mg ..... Cough suppressant
Doxylamine succinate 6.25 mg ..... Antihistamine
Phenylephrine HCl 5 mg ..... Nasal decongestant

Uses ■ temporarily relieves:
- nasal congestion ■ headache ■ cough
- minor aches & pains ■ sinus congestion & pressure
- runny nose and sneezing *(NIGHT only)*
- temporarily 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 *(DAY only)*

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 containing acetaminophen
- 3 or more alcoholic drinks every day while using these products

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 ■ diabetes
- high blood pressure ■ thyroid disease
- trouble urinating due to an enlarged prostate gland
- glaucoma *(NIGHT only)*
- 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
- taking sedatives or tranquilizers *(NIGHT only)*

When using these products
- **do not use more than directed**
- excitability may occur, especially in children *(NIGHT only)*
- marked drowsiness may occur *(NIGHT only)*
- alcohol, sedatives, and tranquilizers may increase drowsiness *(NIGHT only)*
- avoid alcoholic drinks *(NIGHT only)*
- be careful when driving a motor vehicle or operating machinery *(NIGHT only)*

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 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: In case of overdose, get medical help or contact a Poison Control Center right away.

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 at 20-25°C (68-77°F)
- protect from light, heat and moisture

Inactive ingredients (DAY only)
edible printing ink, FD&C Blue no. 1, FD&C Red no. 40, gelatin, glycerin, polyethylene glycol 400, povidone K30, propylene glycol, purified water, sorbitol sorbitan solution

Inactive ingredients (NIGHT only)
edible printing ink, FD&C Blue no. 1, gelatin, glycerin, polyethylene glycol 400, povidone K30, propylene glycol, purified water, sorbitol sorbitan solution

MAXIMUM STRENGTH SINUS RELIEF

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, doxylamine succinate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-824

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-824-12	1 in 1 CARTON; Type 0: Not a Combination Product	12/25/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	16
Part 2	2 BLISTER PACK	8

Part 1 of 2

MAXIMUM STRENGTH SINUS RELIEF DAY

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

Product Information

Item Code (Source)	NDC:76162-825
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	orange	**Score**	no score
Shape	OVAL	**Size**	21mm
Flavor		**Imprint Code**	811
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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 Drug	M012	12/25/2023	

Part 2 of 2

MAXIMUM STRENGTH SINUS RELIEF NIGHT

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

Product Information	
Item Code (Source)	NDC:76162-826
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics			
Color	green	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	812
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 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 Drug	M012	12/25/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/25/2023	

Labeler - Topco Associates LLC (006935977)

Revised: 12/2023 Topco Associates LLC