DAY AND NIGHT SINUS RELIEF MAXIMUM STRENGTH- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, guaifenesin, phenylephrine hydrochloride
Wal-Mart Stores, Inc.

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 Day & Night Sinus Relief

Active ingredients (in each Softgel)

Sinus Daytime

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

Sinus Nighttime

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

Purposes

Sinus Daytime

Pain reliever
Cough suppressant
Expectorant
Nasal decongestant

Sinus Nighttime

Pain reliever
Cough suppressant
Antihistamine
Nasal decongestant

Uses

- temporarily relieves:
- nasal congestion
- headache
- cough
- minor aches and pains
- sinus congestion and pressure
- runny nose and sneezing ***(Nighttime only)***
- temperarily 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 ***(Daytime 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 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
- diabetes
- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- glaucoma ***(Nighttime only)***
- a breathing problem such as emphysema or chronic bronchitis ***(Nighttime 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 ***(Nighttime only)***

When using this product

- **do not use more than directed**
- excitability may occur, especially in children ***(Nighttime only)***
- marked drowsiness may occur ***(Nighttime only)***
- alcohol, sedatives, and tranquilizers may increase drowsiness ***(Nighttime only)***
- avoid alcoholic drinks ***(Nighttime only)***
- be careful when driving a motor vehicle or operating machinery ***(Nighttime 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: 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 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)**
- 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 room temperature 15º-30ºC (59º-86ºF) and avoid excessive heat.

Inactive ingredients

(Daytime only) FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution and white ink

(Nighttime only) D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution and white ink

Questions or comments?

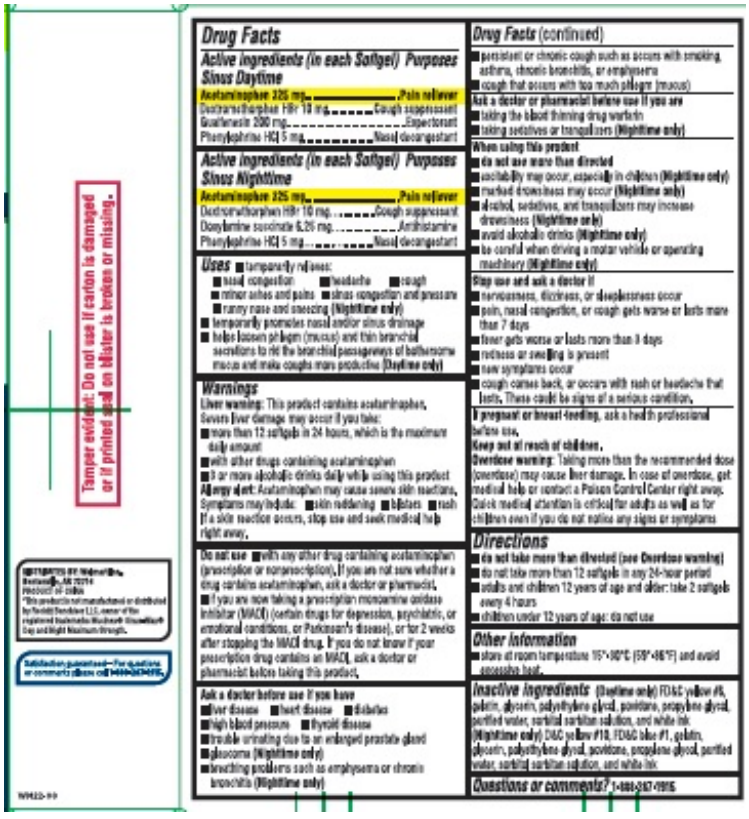
Call toll free: **1-888-287-1915**

PRINCIPAL DISPLAY PANEL - Carton Label

Maximum Strength Day and Night Sinus Relief Combo 24ct

NDC 49035-587-04


DAY & NIGHT TWIN PACK
equate™
MAXIMUM STRENGTH Daytime Sinus Relief
ACETAMINOPHEN 325mg
Dextromethorphan HBr 10mg
Guaifenesin 200mg
Phenylephrine HCl 5mg
MAXIMUM STRENGTH Nighttime Sinus Relief
ACETAMINOPHEN 325mg
Dextromethorphan HBr 10mg
Doxylamine succinate 6.25mg
Phenylephrine HCl 5mg
DAY & NIGHT TWIN PACK
equate™
NDC 0825-0241
Compare to Mucinex® Sinus-Max® Day and Night Maximum Strength Active Ingredients*
Maximum Strength**
Fast Dissolving Softgels
Sinus Relief
Day
ACETAMINOPHEN
Pain Reliever
Dextromethorphan HBr
Cough Suppressant
Guaifenesin
Expectorant
Phenylephrine HCl
Nasal Decongestant
• Relieves sinus pressure, headache & congestion
• Controls cough
• Thins & loosens mucus
Night
ACETAMINOPHEN
Pain Reliever
Dextromethorphan HBr
Cough Suppressant
Doxylamine succinate
Antihistamine
Phenylephrine HCl
Nasal Decongestant
• Relieves nasal congestion, sinus pressure & pain
• Controls cough
• Relieves runny nose & sneezing
16 SOFTGELS (Liquid Filled Capsules)
24 TOTAL
AGES 12+
8 SOFTGELS (Liquid Filled Capsules)
**Per 4-hour dose
Do not take the Daytime and Nighttime 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 Nighttime softgels sooner than 4 hours after the last dose of the Daytime softgels unless directed by a doctor.
Take only as directed.
Keep carton for complete product information
PARENTS:
Learn about teen medication abuse
www.StopMedicineAbuse.org
Check Local Rules
COATED PAPER BOX
MULTI-LAYER TRAY
*Not recycled in all communities
Manufactured in India
LOT NO:
EXP DATE:
COATING FREE AREA
362006
6 81131 27526 2


Tamper evident: Do not use if carton is damaged, or if printed seal on blister is broken or missing.
Drug Facts
Active ingredients (in each Softgel) Purposes
Sinus Daytime
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) Purposes
Sinus Nighttime
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 and pains ■ sinus congestion and pressure
■ runny nose and sneezing (Nighttime 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 (Daytime 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 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.
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 (Nighttime only)
■ breathing problems such as emphysema or chronic bronchitis (Nighttime only)
Drug Facts (continued)
■ 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 (Nighttime only)
When using this product
■ do not use more than directed
■ excitability may occur, especially in children (Nighttime only)
■ marked drowsiness may occur (Nighttime only)
■ alcohol, sedatives, and tranquilizers may increase drowsiness (Nighttime only)
■ avoid alcoholic drinks (Nighttime only)
■ be careful when driving a motor vehicle or operating machinery (Nighttime 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: 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 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)
■ 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 room temperature 15°-30°C (59°-86°F) and avoid excessive heat.
Inactive ingredients (Daytime only) FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, and white ink (Nighttime only) D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, and white ink
Questions or comments? 1-888-287-1915
Satisfaction guaranteed—For questions or comments please call 1-888-287-1915
Distributed by Walmart Inc., Bentonville, AR 72716
Product of China
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W9823-99

DAY AND NIGHT SINUS RELIEF MAXIMUM STRENGTH

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

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49035-587

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49035-587-04	1 in 1 CARTON; Type 0: Not a Combination Product	01/31/2018	

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

Part 1 of 2

DAY SINUS RELIEF

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

Product Information	
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 YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	orange (clear)	**Score**	no score
Shape	CAPSULE (Oblong)	**Size**	25mm
Flavor		**Imprint Code**	PC26
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 CARTON		
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	01/31/2018	

Part 2 of 2

NIGHT SINUS RELIEF

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

Product Information	
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

D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	green (clear)	**Score**	no score
Shape	CAPSULE (Oblong)	**Size**	21mm
Flavor		**Imprint Code**	PC22
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
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	01/31/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/31/2018	

Labeler - Wal-Mart Stores, Inc. (051957769)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(49035-587) , analysis(49035-587)

Revised: 11/2019 Wal-Mart Stores, Inc.