# GREEN GUARD ADVANCED SINUS RELIEF- acetaminophen, phenylephrine hydrochloride tablet Unifirst First Aid Corporation

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.

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#### 819R Green Guard Advanced Sinus Relief

#### **Drug Facts**

### Active ingredients (in each tablet)

Acetaminophen 500 mg

Phenylephrine HCl 5 mg

#### **Purpose**

Pain reliever/fever reducer

Nasal decongestant

#### Uses

temporarily relieves these common cold/flu symptoms:

- nasal congestion
- headache
- minor aches and pains
- stuffy nose
- sinus congestion and pressure

temporarily reduces fever

# Warnings

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

- more than 4,000 mg of acetaminophen in 24 hours
- 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.
- for more than 10 days unless directed by a doctor

# Ask a doctor before use if you have

- liver disease
- thyroid disease
- diabetes
- high blood pressure
- heart disease
- trouble urinating due to an enlarged prostate gland

# Ask a doctor or pharmacist before use if you are

• taking the blood thinning drug warfarin

# When using this product do not exceed recommended dosage.

# Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- pain or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms appear

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 (1-800-222-1222).

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 use more than directed

**Adults and children: (12 years and over)** Take 2 tablets every 6 hours. Do not take more than 8 tablets in 24 hours.

# Children under 12 years: Ask a doctor

#### Other information

- store at room temperature 59°-86°F (15°-30°C)
- tamper evident sealed packets
- do not use any opened or torn packets
- avoid excessive heat and humidity

## Inactive ingredients

corn starch, crospovidone, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, stearic acid.

#### **Questions or comments?** 1-800-869-6970

Advanced Sinus relief™

Acetaminophen 500mg/Acetaminofeno 500mg

Phenylephrine HCl 5mg/Fenilefrina HCl 5mg

Tabletas mejoradas para el alivio sinusal

Pain Reliever & Fever Reducer & Nasal Decongestant / Alivia el dolor y reduce la fiebre y descongestivo nasal

Pull to Open

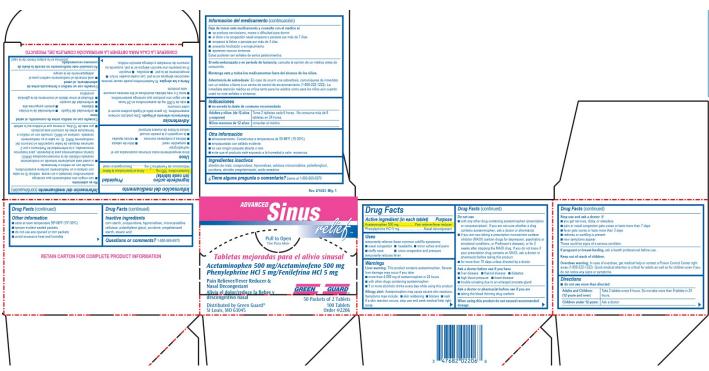
Tire Para Abrir

**GREEN GUARD ®** 

50 Packets of 2 Tablets 100 Tablets

Order #2206

Distributed by Green Guard ®, St Louis, MO 63045



# GREEN GUARD ADVANCED SINUS RELIEF acetaminophen, phenylephrine hydrochloride tablet Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:47682-001

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients		
Ingredient Name	Strength	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
STARCH, CORN (UNII: O8232NY3SJ)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
CROSPOVIDONE (UNII: 68401960MK)		
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)		

Product Characteristics				
Color	white (white)	Score	no score	
Shape	ROUND (ROUND)	Size	12mm	
Flavor		Imprint Code	AZ;261	
Contains				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:47682-001- 33	50 in 1 BOX	12/30/2008		
1		2 in 1 PACKET; Type 0: Not a Combination Product			
2	NDC:47682-001- 48	125 in 1 BOX	12/30/2008		
2	NDC:47682-001- 99	2 in 1 PACKET; Type 0: Not a Combination Product			
3	NDC:47682-001- 99	2 in 1 PACKET; Type 0: Not a Combination Product	12/30/2008		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/30/2008	