

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.

819R GG 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

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 older) 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, croscopovidone*, FD&C blue #1*, hypromellose*, microcrystalline cellulose, polyethylene glycol*, povidone, pregelatinized starch*, sodium starch glycolate*, stearic acid.

*may contain

Questions or comments? 1-800-869-6970

Green Guard Advanced Sinus Relief Label

Advanced Sinus relief™

Tabletas mejoradas para el alivio sinusal

GREEN GUARD®

Pull to Open

Tire Para Abrir

Acetaminophen 500mg/Acetaminofeno 500 mg

Phenylephrine HCl 5mg/Fenilefrina HCl 5 mg

Pain Reliever/Fever reducer/ & Nasal Decongestant/ Alivia el dolor y reduce la fiebre y decongestivo nasal

125 Packets of 2 Tablets

250 Tablets

Order #2207

Distributed by Green Guard®, St Louis, MO 63045

<p>ADVANCED Sinus relief™</p> <p>Tabletas mejoradas para el alivio sinusal</p> <p>Información del medicamento (continuación)</p> <p>Deje de tomar este medicamento y consulte con el médico si:</p> <ul style="list-style-type: none"> no produce mejoría, mejora o dificultad para dormir el dolor de la congestión nasal empeora o persiste por más de 7 días persiste la fiebre o persiste por más de 3 días aparecen nuevos síntomas <p>Estos podrían ser señales de serios padecimientos.</p> <p>Si está embarazada o en período de lactancia, consulte la opinión de un médico antes de continuar.</p> <p>Mantenga este y todos los medicamentos fuera del alcance de los niños.</p> <p>Advertencia de sobredosis: En caso de ocurrir una sobredosis, comuníquese de inmediato con un médico o llame a un centro de control de envenenamiento (1-800-222-1222). La información médica es crítica para los médicos como para los niños así cuando usted no está seguro o si ocurre.</p> <p>Indicaciones</p> <ul style="list-style-type: none"> no exceda la dosis de consumo recomendada <p>Información del medicamento (continuación)</p> <p>Adultos y niños: Tome 2 tabletas cada 6 horas. No consuma más de 8 tabletas en 24 horas.</p> <p>Siempre consulte al médico antes de tomar.</p> <p>Méjica: consulte al médico antes de tomar.</p> <p>Otra información</p> <ul style="list-style-type: none"> El almacenamiento: Conserve a temperatura de 59-86°F (15-30°C) El empaque: Con envase de aluminio. no use ningún paquete abierto o roto deje que el producto se espere a la humedad y calor excesivos <p>Ingredientes inactivos</p> <p>amido de maíz, croscopovidona*, azul FD&C#1*, hipromelosa*, celulosa microcristalina, polietileno glicol*, povidona, almidón pregelatinizado*, almidón glicolato sodio*, ácido estearico</p> <p>¿Tiene alguna pregunta o comentario?</p> <p>Llame al 1-800-869-6970</p> <p>CONSERVE LA CAJA PARA OBTENER LA INFORMACIÓN COMPLETA DEL PRODUCTO</p>	<p>ADVANCED Sinus relief™</p> <p>Tabletas mejoradas para el alivio sinusal</p> <p>GREEN GUARD®</p> <p>Pull to Open Tire Para Abrir</p> <p>Acetaminophen 500 mg/Acetaminofeno 500 mg Phenylephrine HCl 5 mg/Fenilefrina HCl 5 mg</p> <p>Pain Reliever/Fever Reducer & Nasal Decongestant Alivia el dolor/reduce la fiebre y descongestivo nasal</p> <p>125 Packets of 2 Tablets 250 Tablets Order #2207</p> <p>Distributed by Green Guard® St Louis, MO 63045</p>	<p>Drug Facts</p> <p>Active ingredient (in each tablet) Purpose Acetaminophen 500 mg Pain reliever/fever reducer Phenylephrine HCl 5 mg Nasal decongestant</p> <p>Uses</p> <p>temporarily relieves these common cold/flu symptoms:</p> <ul style="list-style-type: none"> nasal congestion headache minor aches and pains stuffy nose sinus congestion and pressure <p>temporarily reduces fever</p> <p>Warnings</p> <p>Use warning: This product contains acetaminophen. Severe liver damage may occur if you take:</p> <ul style="list-style-type: none"> more than 4,000 mg of acetaminophen in 24 hours with other drugs containing acetaminophen if or more alcohol drinks every day while using this product <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: hives, skin redness, blisters, or rash. If a skin reaction occurs, stop use and seek medical help right away.</p> <p>Do not use</p> <ul style="list-style-type: none"> 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 use any tablet or 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. if more than 10 days unless directed by a doctor. <p>Ask a doctor before use if you have:</p> <ul style="list-style-type: none"> liver disease kidney disease high blood pressure heart disease trouble emptying the bladder or an enlarged prostate gland <p>Ask a doctor or pharmacist before use if you are:</p> <ul style="list-style-type: none"> pregnant or breastfeeding taking the blood thinning drug warfarin. <p>Drug Facts (continued)</p> <p>When using this product do not exceed recommended dosage.</p> <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> you get nervous, dizzy, or drowsy your nasal congestion gets worse or lasts more than 7 days your eyes become red or itchy more than 3 days itchiness or swelling is present skin symptoms appear <p>These could be signs of a serious condition.</p> <p>If pregnant or breast feeding, ask a health professional before use.</p> <p>Keep out of reach of children.</p> <p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> do not use more than directed <p>Adults and Children (12 years and older) Take 2 tablets every 6 hours. Do not take more than 8 tablets in 24 hours.</p> <p>Children under 12 years: Ask a doctor.</p> <p>Other information</p> <ul style="list-style-type: none"> store at room temperature 59-86°F (15-30°C) keep out of reach of children do not use any opened or torn packets do not use any expired or torn packets do not use near heat and humidity <p>Inactive ingredients</p> <p>corn starch, croscopovidona*, FD&C blue #1*, hypromelosa*, microcristalina celulosa, polietileno glicol*, povidona, pregelatinizado almidón*, almidón glicolato sodio*, ácido estearico</p> <p>*may contain</p> <p>Questions or comments? 1-800-869-6970</p> <p>RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION</p>	<p>Información del medicamento</p> <table border="1"> <thead> <tr> <th>Ingredientes activos (en cada tableta)</th> <th>Propiedad</th> </tr> </thead> <tbody> <tr> <td>Acetaminofeno 500 mg</td> <td>Alivia el dolor/reduce la fiebre</td> </tr> <tr> <td>Clorhidrato de Fenilefrina 5 mg</td> <td>Descongestivo nasal</td> </tr> </tbody> </table> <p>Usos</p> <p>temporalmente alivia estos síntomas comunes del resfriado/gripe:</p> <ul style="list-style-type: none"> congestión nasal dolor de cabeza dolores y molestias menores narices tapadas <p>temporalmente reduce la fiebre</p> <p>Advertencia de sobredosis</p> <p>Este producto contiene acetaminofeno. Un grave daño al hígado podría ocurrir si usted consume:</p> <ul style="list-style-type: none"> más de 4,000 mg de acetaminofeno en 24 horas con algún otro producto que contenga acetaminofeno si toma 3 o más bebidas alcohólicas al día mientras consume este producto <p>Alerta de los alergias: El acetaminofeno puede causar serias reacciones alérgicas en la piel. Las cuales pueden incluir: erupción de la piel, ampollas, o hinchazón. Si se presenta una reacción alérgica en la piel, suspenda su consumo de inmediato y obtenga atención médica.</p> <p>No se administre</p> <ul style="list-style-type: none"> con ningún otro medicamento que contenga acetaminofeno (recetado o sin receta médica) si no sabe con certeza si un medicamento contiene acetaminofeno, consulte con un médico o farmacéutico. si usted está actualmente tomando un medicamento recetado inhibidor de la monoaminooxidasa (MAOI) (ciertos medicamentos para la depresión, para trastornos emocionales, o la enfermedad de Parkinson) o por 2 semanas después de haber suspendido el consumo del medicamento MAOI. Si no sabe si su medicamento recetado contiene un MAOI, consulte con un médico o farmacéutico antes de consumir este producto. por más de 10 días, a menos que el médico así lo señale. <p>Consulte con un médico antes de consumirlo, si usted tiene:</p> <ul style="list-style-type: none"> enfermedad del hígado enfermedad de la vesícula presión sanguínea alta enfermedad del corazón dificultad al vaciar la vejiga o el aumento de la glándula prostática diabetes enfermedad del corazón <p>Consulte con un médico o farmacéutico antes de administrárselo, si usted:</p> <ul style="list-style-type: none"> está tomando el medicamento warfarin para el adelgazamiento de la sangre <p>Al consumir este medicamento no exceda la dosis de consumo recomendada</p>	Ingredientes activos (en cada tableta)	Propiedad	Acetaminofeno 500 mg	Alivia el dolor/reduce la fiebre	Clorhidrato de Fenilefrina 5 mg	Descongestivo nasal
Ingredientes activos (en cada tableta)	Propiedad								
Acetaminofeno 500 mg	Alivia el dolor/reduce la fiebre								
Clorhidrato de Fenilefrina 5 mg	Descongestivo nasal								

GREEN GUARD ADVANCED SINUS RELIEF

acetaminophen, phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47682-002
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	blue (blue)	Score	no score
Shape	ROUND (ROUND)	Size	12mm
Flavor		Imprint Code	FR33
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-002-33	50 in 1 BOX	12/30/2008	07/01/2024
1	NDC:47682-002-99	2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:47682-002-48	125 in 1 BOX	12/30/2008	07/01/2024
2	NDC:47682-002-99	2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:47682-002-99	2 in 1 PACKET; Type 0: Not a Combination Product	12/30/2008	07/01/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/30/2008	07/01/2024

Revised: 3/2023

Unifirst First Aid Corporation