

## **GREEN GUARD PAIN AND ACHE RELIEF- acetaminophen, aspirin, salicylamide and caffeine 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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### **Green Guard Pain & Ache Relief**

#### **Drug Facts**

##### **Active ingredient (in each tablet)**

Acetaminophen 110 mg

Aspirin (NSAID)\* 162 mg

Caffeine 32.4 mg

Salicylamide (NSAID)\* 152 mg

\*nonsteroidal anti-inflammatory drug

#### **Purpose**

Pain reliever/Fever reducer

Pain reliever/Fever reducer

Adjuvant

Pain reliever aid

#### **Uses**

temporarily relieves minor aches and pains associated with

- headache
- muscular aches
- minor arthritis pain
- back pain
- colds
- toothache
- menstrual cramps

Temporarily reduces fever.

#### **Warnings**

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:** Aspirin (NSAIDs) may cause a severe allergic reaction which may include:

■ hives ■ facial swelling ■ asthma (wheezing) ■ shock

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

■ skin reddening ■ blisters ■ rash

If a skin or allergic reaction occurs, stop use and seek medical help right away.

**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

**Stomach bleeding warning:** This product contains nonsteroidal anti-inflammatory drugs (NSAIDs), which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

**Caffeine warning:** The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat

**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.

- for pain for more than 10 days unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor
- with any other pain reliever/fever reducer

**Ask a doctor before use if**

- stomach bleeding warning applies to you
- you have a history of stomach problems (such as heartburn, upset stomach or stomach pain)
- you have heart disease, liver cirrhosis, or kidney disease
- you have asthma or high blood pressure
- you are taking a diuretic

**Ask a doctor or pharmacist before use if you are taking a prescription drug for**

- anticoagulation
- diabetes
- gout

■ arthritis

**Ask a doctor or pharmacist before use if you have**

■ liver disease

**When using this product do not exceed recommended dose**

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding: ■ feel faint ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better
- symptoms do not improve
- pain or fever gets worse
- ringing in the ears or loss of hearing occurs
- new symptoms occur

**If pregnant or breast-feeding, ask a health care professional before use. It is especially important not to use aspirin and salicylamide during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery**

**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. Prompt 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 4 hours as needed with a full glass of water. Do not exceed 8 tablets in 24 hours or as directed by a doctor.

**Children under 12 years of age:** ask a doctor

**Other information**

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

**Inactive ingredients**

FD&C yellow #6, magnesium stearate, microcrystalline cellulose, povidone, starch, stearic acid.

**Questions or Comments?** 1-800-869-6970

**Green Guard Pain & Ache Relief**

Pain & Ache Relief™

Tabletas para aliviar el dolor

Green Guard®

Pull Out

Tire Para Abrir

Acetaminophen/Acetaminofeno 110 mg

Aspirin (NSAID)/Aspirina (AINE) 162 mg

Salicylamide (NSAID)/ Salicilamida (AINE) 152 mg

Caffeine/Cafeina 32.4 mg

Pain Reliever & Fever Reducer/ Alivia el dolor y reduce la fiebre

125 packets of 2 tablets

250 Tablets Order #2210

Distributed by Green Guard®, St Louis, MO 63045

**CONSERVE LA CALA PARA OBTENER LA INFORMACION COMPLETA DEL PRODUCTO**

Si se consume más de lo que se indica...

**Información del medicamento (continuación)**

Advertencia sobre la cafeína: La dosis recomendada de este producto, contiene cafeína,...

**Indicaciones**

Adultos y niños: Tome 2 tabletas cada 4 horas como la necesita con un vaso lleno de agua. No consuma más de 12 tabletas en 24 horas, o haga lo que el médico le indique.

Niños menores de 12 años: Consultar al médico.

**Otra información**

Almacenamiento: conserve a temperatura ambiente 59-86°F (15-30°C).

**Ingredientes inactivos**

amiloil F5C #5, extracto de magnesia, celulosa microcristalina, povidona, almidón, ácido succínico.

¿Tiene alguna pregunta o comentario? Llame al 1-800-669-6970

**Pain & Ache relief**

Pull to Open  
Tire Para Abrir

**Tabletas para aliviar el dolor**

Acetaminophen/Acetaminofeno 110 mg  
Aspirin (NSAID)/Aspirina (AINE) 162 mg  
Salicylamide (NSAID)/Salicilamida (AINE) 152 mg  
Caffeine/Cafeina 32.4 mg

Pain Reliever/Fever Reducer  
Alivia el Dolor/Reduce la Fiebre

Distributed by Green Guard®  
St. Louis, MO 63045

50 Packets of 2 Tablets  
100 Tablets  
Order #2209

**Información del medicamento (continuación)**

Si está embarazada o en período de lactancia, consulte a un médico antes de consumir este producto. Es sobre todo importante que no se consuma aspirina durante los últimos 3 meses del embarazo, a menos que el médico así se lo haya prescrito, ya que esto podría causar problemas a la criatura que está por nacer o traer complicaciones durante el parto. Mantenga este y todos los medicamentos fuera del alcance de los niños.

Mantenga este y todos los medicamentos fuera del alcance de los niños.

Advertencia de sobredosis: Consumir más de la dosis recomendada (sobredosis) puede causar daño al hígado. En caso de ocurrir una sobredosis, contáctese de inmediato con un médico o llame a un centro de control de envenenamientos 1-800-525-1222. La medicina attention médica es crítica tanto para los adultos como para los niños aun cuando usted no sienta náuseas o vómitos.

**Indicaciones**

Adultos y niños: Tome 2 tabletas cada 4 horas como la necesita con un vaso lleno de agua. No consuma más de 12 tabletas en 24 horas, o haga lo que el médico le indique.

Niños menores de 12 años: Consultar al médico.

**Otra información**

Almacenamiento: conserve a temperatura ambiente 59-86°F (15-30°C).

Evite exponerlo al calor y humedad excesiva.

Almacene con niños o niños.

No use este medicamento si usted está tomando otros medicamentos que contengan aspirina o salicilato.

**Ingredientes inactivos**

amiloil F5C #5, extracto de magnesia, celulosa microcristalina, povidona, almidón, ácido succínico.

¿Tiene alguna pregunta o comentario? Llame al 1-800-669-6970

# GREEN GUARD PAIN AND ACHE RELIEF

acetaminophen, aspirin, salicylamide and caffeine tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC: 47682-003
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	110 mg	
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	162 mg	
<b>SALICYLAMIDE</b> (UNII: EM8BM710ZC) (SALICYLAMIDE - UNII:EM8BM710ZC)	SALICYLAMIDE	152 mg	
<b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	32.4 mg	

## Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STARCH, CORN (UNII: O8232NY3SJ)	

## Product Characteristics

Color	orange (orange)	Score	no score
Shape	ROUND (ROUND)	Size	11mm
Flavor		Imprint Code	FR;2
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-003-33	50 in 1 BOX	12/30/2008	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:47682-003-48	125 in 1 BOX	12/30/2008	
2	NDC:47682-003-99	2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:47682-003-99	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 not final	part343	12/30/2008	

**Labeler** - Unifirst First Aid Corporation (832947092)

## Establishment

Name	Address	ID/FEI	Business Operations
Prestige Packaging		080667761	pack(47682-003)