

**PAIN RELIEVER PLUS- acetaminophen, aspirin and caffeine tablet, film coated**  
**Avera McKennan Hospital**

*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.*

-----

**Major 44-159B**

***Active ingredients (in each tablet)***

Acetaminophen 250 mg  
Aspirin 250 mg (NSAID)\*  
Caffeine 65 mg

\*nonsteroidal anti-inflammatory drug

***Purpose***

Pain reliever  
Pain reliever  
Pain reliever aid

***Uses***

- temporarily relieves minor aches and pains due to:
  - headache
  - a cold
  - arthritis
  - muscular aches
  - sinusitis
  - toothache
  - premenstrual and menstrual cramps

***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 may cause a severe allergic reaction, which may include:

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

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

- more than 8 tablets 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

**Stomach bleeding warning:** This product contains an NSAID, 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 heartbeat.

**Do not use**

- if you ever had an allergic reaction to acetaminophen, aspirin, or any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or non prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

**Ask a doctor before use if**

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

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

- taking a prescription drug for diabetes, gout, or arthritis
- taking any other drug or are under a doctor's care for any serious condition

**Stop use and ask a doctor if**

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - have bloody or black stools
  - vomit blood
  - have stomach pain that does not get better
- an allergic reaction occurs. Seek medical help right away.
- any new symptoms appear
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- painful area is red or swollen

**If pregnant or breast-feeding,**

ask a health professional before use. It is especially important not to use aspirin 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.**

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 use more than directed**
- drink a full glass of water with each dose
- 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 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

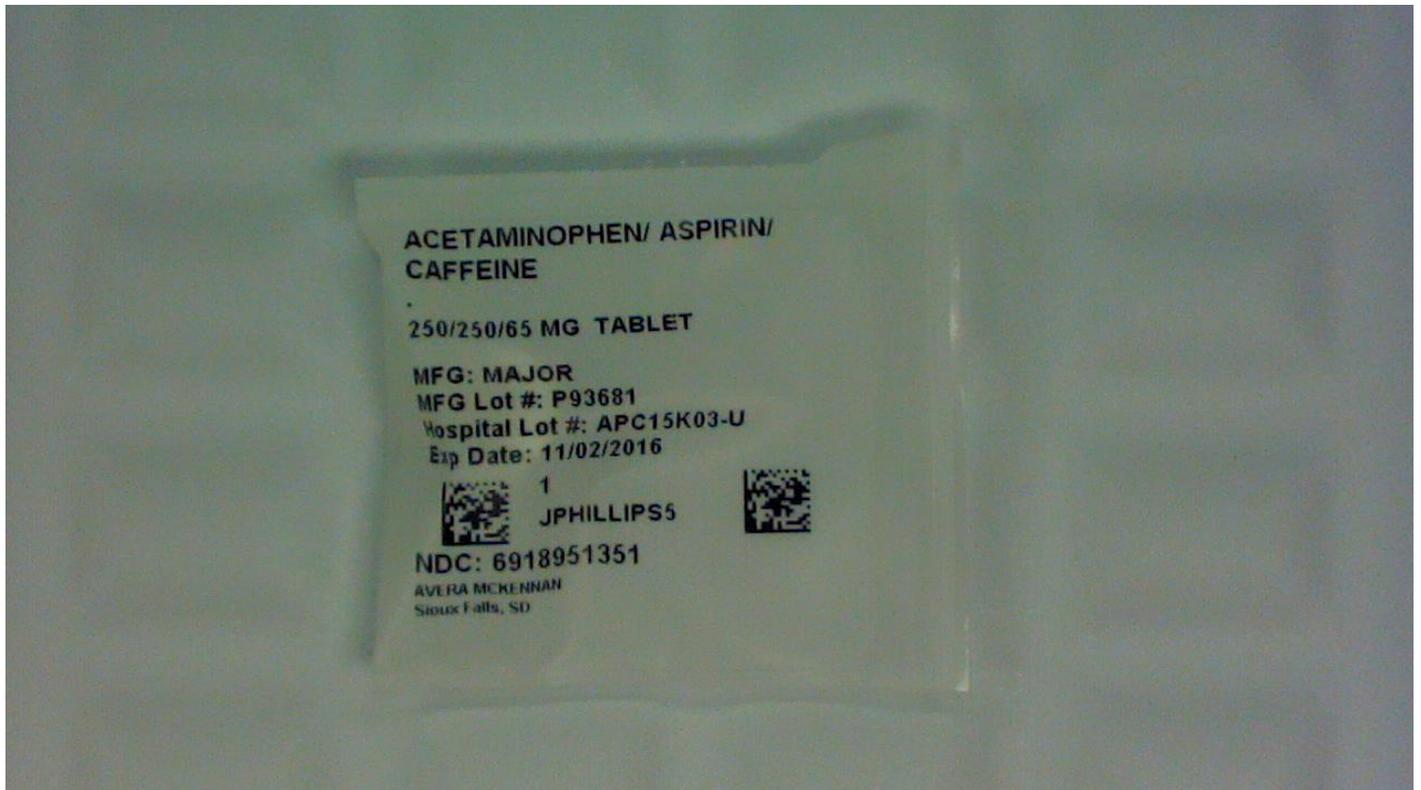
### ***Inactive ingredients***

corn starch, crospovidone, hypromellose, microcrystalline cellulose, povidone, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

### ***Questions or comments?***

**(800) 616-2471**

### **Principal Display Panel**



## **PAIN RELIEVER PLUS**

acetaminophen, aspirin and caffeine tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69189-5135(NDC:0904-5135)
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

## Inactive Ingredients

Ingredient Name	Strength
CROSPVIDONE (UNII: 68401960MK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONES (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	44;159
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69189-5135-1	1 in 1 DOSE PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	04/14/2015	

**Labeler** - Avera McKennan Hospital (068647668)

**Establishment**

Name	Address	ID/FEI	Business Operations
Avera McKennan Hospital		068647668	relabel(69 189-5135) , repack(69 189-5135)

Revised: 1/2016

Avera McKennan Hospital