

**ACETAMINOPHEN ASPIRIN AND CAFFEINE - acetaminophen, aspirin and caffeine tablet, film coated**  
**Better Living Brands, LLC**

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**Acetaminophen, Aspirin (NSAID) and Caffeine Tablets USP**

***Drug Facts***

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

Acetaminophen USP 250 mg

Aspirin USP 250 mg (NSAID\*)

Caffeine USP 65 mg

\*nonsteroidal anti-inflammatory drug

***Purposes***

Pain reliever

Pain reliever

Pain reliever aid

***Use***

- treats migraine

***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:** 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.

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

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

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

- more than 2 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

**Medication overuse headache warning:** Headaches may worsen if this product is used for 10 or more days per month.

**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**

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

### **Ask a doctor before use if**

- you have never had migraines diagnosed by a health professional
- you have a headache that is different from your usual migraines
- you have the worst headache of your life
- you have fever and stiff neck
- you have headaches beginning after or caused by head injury, exertion, coughing or bending
- you experienced your first headache after the age of 50
- you have daily headaches
- you have a migraine so severe as to require bed rest
- 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 are taking a diuretic
- you have asthma

- you have problems or serious side effects from taking pain relievers or fever reducers
- you have vomiting with your migraine headache

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

- taking a prescription drug for:
  - diabetes
  - gout
  - arthritis
- under a doctor's care for any serious condition
- taking any other drug
- taking any other product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer

**Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- 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
- your migraine is not relieved or worsens after first dose
- new or unexpected symptoms occur
- ringing in the ears or loss of hearing occurs

**If pregnant or breast-feeding,**

ask a health professional before use. It is especially important not to use aspirin at 20 weeks or later in 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 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: take 2 tablets with a glass of water
- if symptoms persist or worsen, ask your doctor
- do not take more than 2 tablets in 24 hours, unless directed by a doctor
- under 18 years of age: ask a doctor

### **Other information**

- store at controlled room temperature 20°-25°C (68°-77°F)
- close cap tightly after use
- read all product information before using. Keep this box for important information.

### **Inactive ingredients**

crospovidone, glyceryl monostearate, low-substituted hydroxypropyl cellulose, microcrystalline cellulose, polyvinyl alcohol, povidone, pregelatinized starch (maize), sodium lauryl sulfate, stearic acid, talc and titanium dioxide.

### **Questions or comments?**

call **1-855-274-4122** (Monday – Friday 8:30 AM to 5:00 PM EST)

**DISTRIBUTED BY: BETTER LIVING BRANDS LLC**  
P.O.BOX 99, PLEASANTON, CA 94566-0009  
‡1-888-723-3929

Made in India

Code: AP/DRUGS/04/2016

### **PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 250 mg/250 mg/65 mg Container Label - 24 Tablets**

**Signature** **NDC 21130-074-07**  
**Care®**  
Quality Guaranteed

**Migraine Relief**  
**Acetaminophen, Aspirin (NSAID)**  
**and Caffeine Tablets USP**  
**250 mg/250 mg/65 mg**

**Pain Reliever/Pain Reliever Aid**  
**24 Tablets**

### **Top Layer Printing side**

 <b>Migraine Relief</b> Acetaminophen, Aspirin (NSAID) and Caffeine Tablets USP 250 mg/250 mg/65 mg Pain Reliever/Pain Reliever Aid 24 Tablets	NDC 21130-074-07	<b>Do not use if seal imprinted with SEALED for YOUR PROTECTION under the bottle cap is broken or missing. READ ALL PRODUCT INFORMATION BEFORE USING. KEEP BOX FOR IMPORTANT INFORMATION.</b>	Lift Here for <i>Drug Facts</i> → 
	<b>DISTRIBUTED BY: BETTER LIVING BRANDS LLC</b> P.O.BOX 99 PLEASANTON, CA 94566-0009 1-888-723-3929 RD 23101 S6289 Made in India Code: AP/DRUGS/04/2016	 PLASTIC BOTTLE www.betterliving.com	P1432651 LM-5271

\* Lot XXXXXXXXXX  
 EXP: MM/YYYY  
 pre-printed batch details  
 should be verified online  
 during packing.

## Top Layer Adhesive side

P1432651 LM-5271	<b>Drug Facts</b>		Gluing Area	
	<b>Active ingredients (in each tablet)</b>			<b>Purposes</b>
	Acetaminophen USP 250 mg	Pain reliever		
	Aspirin USP 250 mg (NSAID*)	Pain reliever		
	Caffeine USP 65 mg	Pain reliever aid		
	*nonsteroidal anti-inflammatory drug			
	<b>Use</b> ■ treats migraine			
	<b>Warnings</b>			
	<b>Reye's syndrome:</b> 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.			
	<b>Allergy alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash. If a skin reaction occurs, stop use and		➔	

## 2nd Layer Printing side

Gluing Area	<b>Drug Facts (continued)</b>		P1432651 LM-5271
	seek medical help right away. <b>Allergy alert:</b> Aspirin may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock. <b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 2 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. <b>Stomach bleeding warning:</b> 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. <b>Medication overuse headache warning:</b> Headaches may worsen if this product is used for 10 or more days per month. <b>Caffeine warning:</b> 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. <b>Do not use</b> ■ if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer ■ with any other drug containing acetaminophen (prescription or nonprescription), if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. <b>Ask a doctor before use if</b> ■ you have never had migraines diagnosed by a health professional ■ you have a headache that is different from your usual migraines ■ you have the worst headache of your life ■ you have fever and		

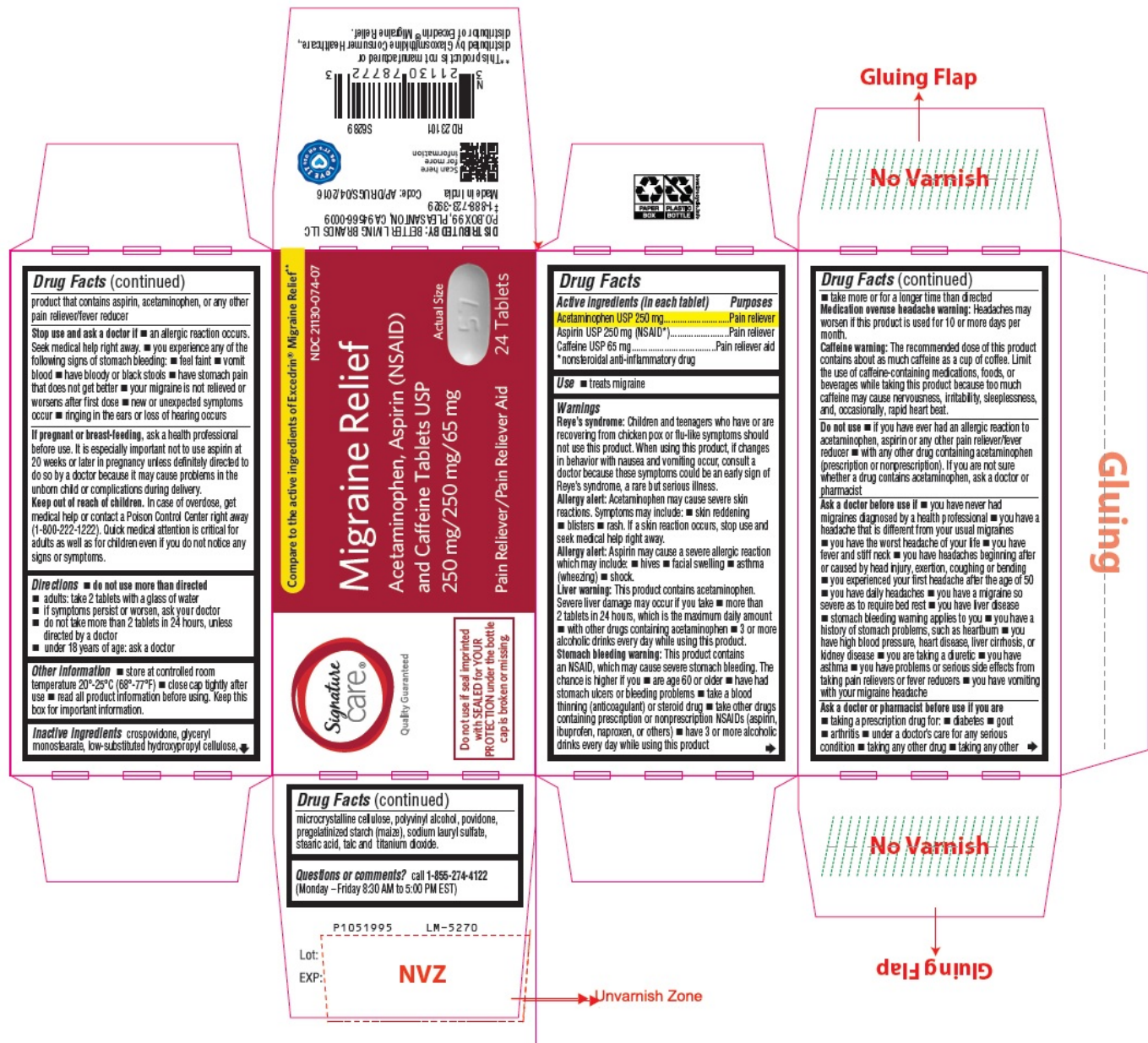
## 2nd Layer Adhesive side

Gluing Area	<b>Drug Facts (continued)</b>		Gluing Area
	stiff neck ■ you have headaches beginning after or caused by head injury, exertion, coughing or bending ■ you experienced your first headache after the age of 50 ■ you have daily headaches ■ you have a migraine so severe as to require bed rest ■ 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 are taking a diuretic ■ you have asthma ■ you have problems or serious side effects from taking pain relievers or fever reducers ■ you have vomiting with your migraine headache. <b>Ask a doctor or pharmacist before use if you are</b> ■ taking a prescription drug for: ■ diabetes ■ gout ■ arthritis ■ under a doctor's care for any serious condition ■ taking any other drug ■ taking any other product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer. <b>Stop use and ask a doctor if</b> ■ an allergic reaction occurs. Seek medical help right away. ■ 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 ■ your migraine is not relieved or worsens after first dose ■ new or unexpected symptoms occur ■ ringing in the ears or loss of hearing occurs. <b>If pregnant or breast-feeding</b> , ask a health professional before use. It is especially important not to use aspirin at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. <b>Keep out of reach of children.</b> 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		

## Base Layer

Gluing Area	<b>Drug Facts (continued)</b>	
	signs or symptoms. <b>Directions</b> ■ <b>do not use more than directed</b> ■ adults: take 2 tablets with a glass of water ■ if symptoms persist or worsen, ask your doctor ■ do not take more than 2 tablets in 24 hours, unless directed by a doctor ■ under 18 years of age: ask a doctor <b>Other information</b> ■ store at controlled room temperature 20°-25°C (68°-77°F) ■ close cap tightly after use ■ read all product information before using. Keep this box for important information. <b>Inert ingredients</b> croscarmellose, croscarmellose, croscarmellose, low substituted hydroxypropyl cellulose	





# ACETAMINOPHEN ASPIRIN AND CAFFEINE

acetaminophen, aspirin and caffeine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-074
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	250 mg

<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
<b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CROSPROVIDONE (120 .MU.M)</b> (UNII: 68401960MK)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 2165RE0K14)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>POVIDONE K90</b> (UNII: RDH86HJV5Z)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	WHITE (White to off-White)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (biconvex)	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	T;57
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-074-07	1 in 1 CARTON	08/11/2023	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:21130-074-14	1 in 1 CARTON	08/11/2023	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:21130-074-21	1 in 1 CARTON	08/11/2023	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211695	08/11/2023	



**Labeler** - Better Living Brands, LLC (009137209)

**Registrant** - Aurohealth LLC (078728447)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
APL HEALTHCARE LIMITED		650918514	ANALYSIS(21130-074) , MANUFACTURE(21130-074)

Revised: 8/2023

Better Living Brands, LLC