

ARAMARK PAIN-FREE EXTRA STRENGTH- acetaminophen, aspirin, caffeine tablet

Western First Aid Safety DBA Aramark

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.

Aramark Pain-Free Extra Strength

Drug Facts

Extra Strength Pain Reliever M560L

Active Ingredients (in each tablet)

Acetaminophen 250 mg

Aspirin (NSAID) 250 mg

Caffeine 65 mg

AcetaminophenPain Reliever/Fever Reducer

Aspirin (NSAID)Pain Reliever/Fever Reducer

CaffeineAdjuvent

Uses:

Temporarily Relieves minor aches and pains

associated with: • backach • headaches

• colds • toothache • minor arthritis pain

• muscular aches • menstrual cramps

Warnings:

• **Reye's Syndrome:** Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye's Syndrome, a rare but serious illness reported to be associated with aspirin.

• **Allergy Alert** - Do not use:

• if you are allergic to aspirin or any other salicylate

• if you have ever had an allergic reaction to any other pain reliever/fever reducer

• **Liver Warning:** This product contains acetaminophen.

Severe liver damage may occur if you take:

• more than 8 tablets in 24 hours

• with other drugs containing acetaminophen (Prescription or nonprescription)

• Ask a doctor or pharmacist before using with other drugs if you are not sure.

• 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 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 an NSAID (aspirin, ibuprofen, naproxen, or others)
 - take more or for a longer time than directed
- **Do not use:**
 - with any other pain reliever/fever reducer
 - for pain for more than 10 days or for fever for more than 3 days unless directed by a doctor
 - if you have ever had an allergic reaction to any other pain reliever/fever reducer

Ask a doctor before using if you have:

- upset stomach or stomach pain • gastric ulcers
- bleeding problems • asthma

Ask a doctor or pharmacist before use if you are

taking a prescription drug for:

- anticoagulation (thinning of blood)
- gout
- diabetes
- arthritis

When using this product do not exceed the recommended dose.

Stop use and ask a doctor if:

- ringing in the ears or loss of hearing occurs
- pain or fever persists or gets worse
- new symptoms occur
- redness or swelling is present

If pregnant or breast-feeding baby, ask a health professional before use. IT IS ESPECIALLY IMPORTANT NOT TO USE ASPIRIN DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFICALLY 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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions:

2 tablets as

DIRECTIONS:

- Adults and children 12 years of age and older:
- Children under 12 years:

needed for pain every 6 hours. Do not exceed 8 tablets in 24 hours or as directed by a doctor.

Consult a doctor.

Other information:

read all warnings and directions before use. Keep carton. Store at 20-25°C (68-77°F) avoid excessive heat above 40°C (104°F)

Inactive Ingredients:

Hydroxypropyl Methylcellulose, Microcrystalline Cellulose, Polyethylene Glycol, Povidone, Sodium Starch Glycoate, Stearic Acid, Titanium Dioxide

Package Labeling

aramark

**100 TABLETS Part # 547R23
PER BOX**

**Pain-Free[®] Extra Strength
Maximum Strength
Pain Reliever**

Temporary relief of fever and the pain of Sinusitis, headache, toothache, muscular aches, backache, menstrual discomfort, minor arthritis pain and colds and flu.

**Compare active ingredient to:
EXCEDRIN Migraine[®]
Registered Trademark of GlaxoSmithKline**

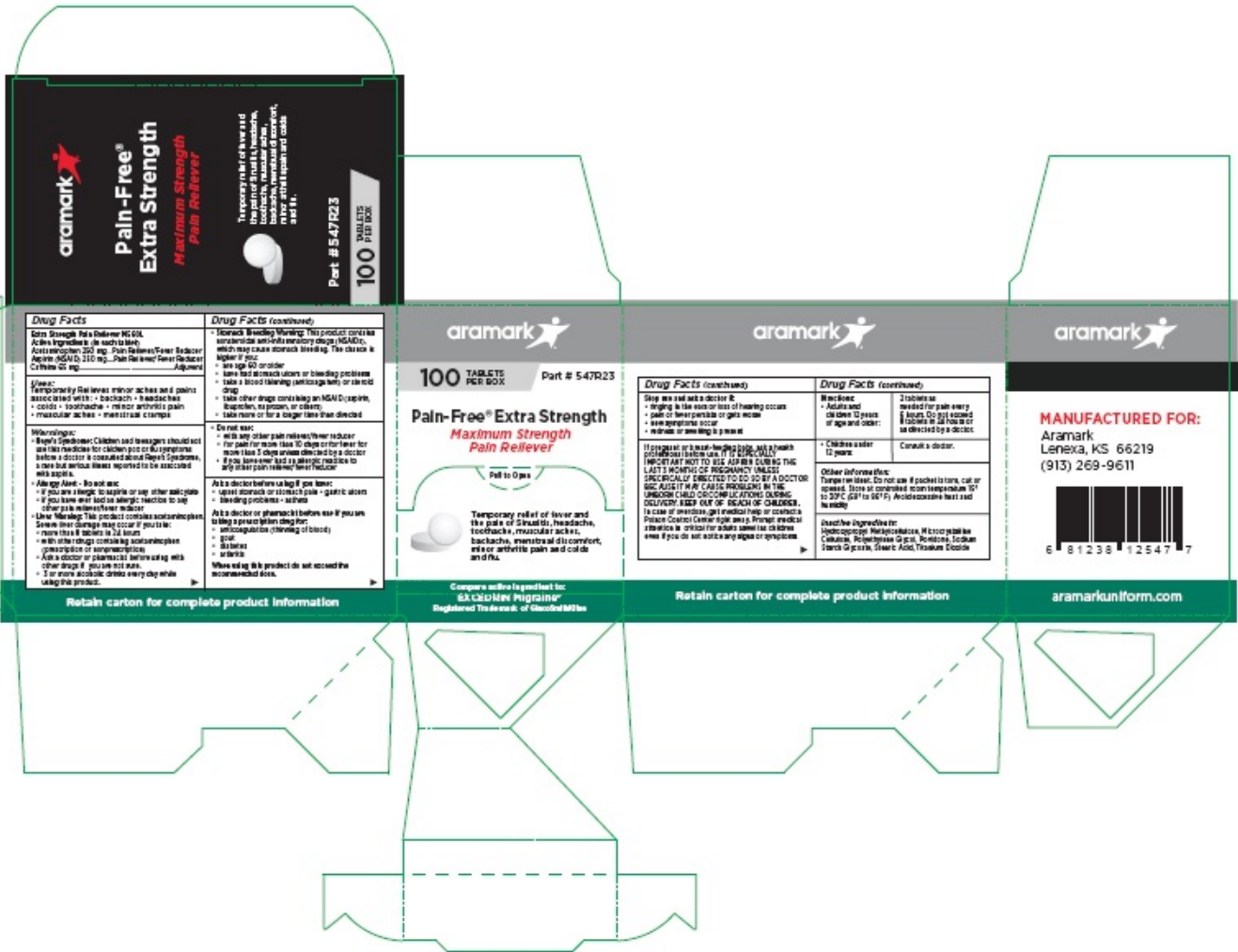
MANUFACTURED FOR:

**Aramark
Lenexa, KS 66219
(913) 269-9611**

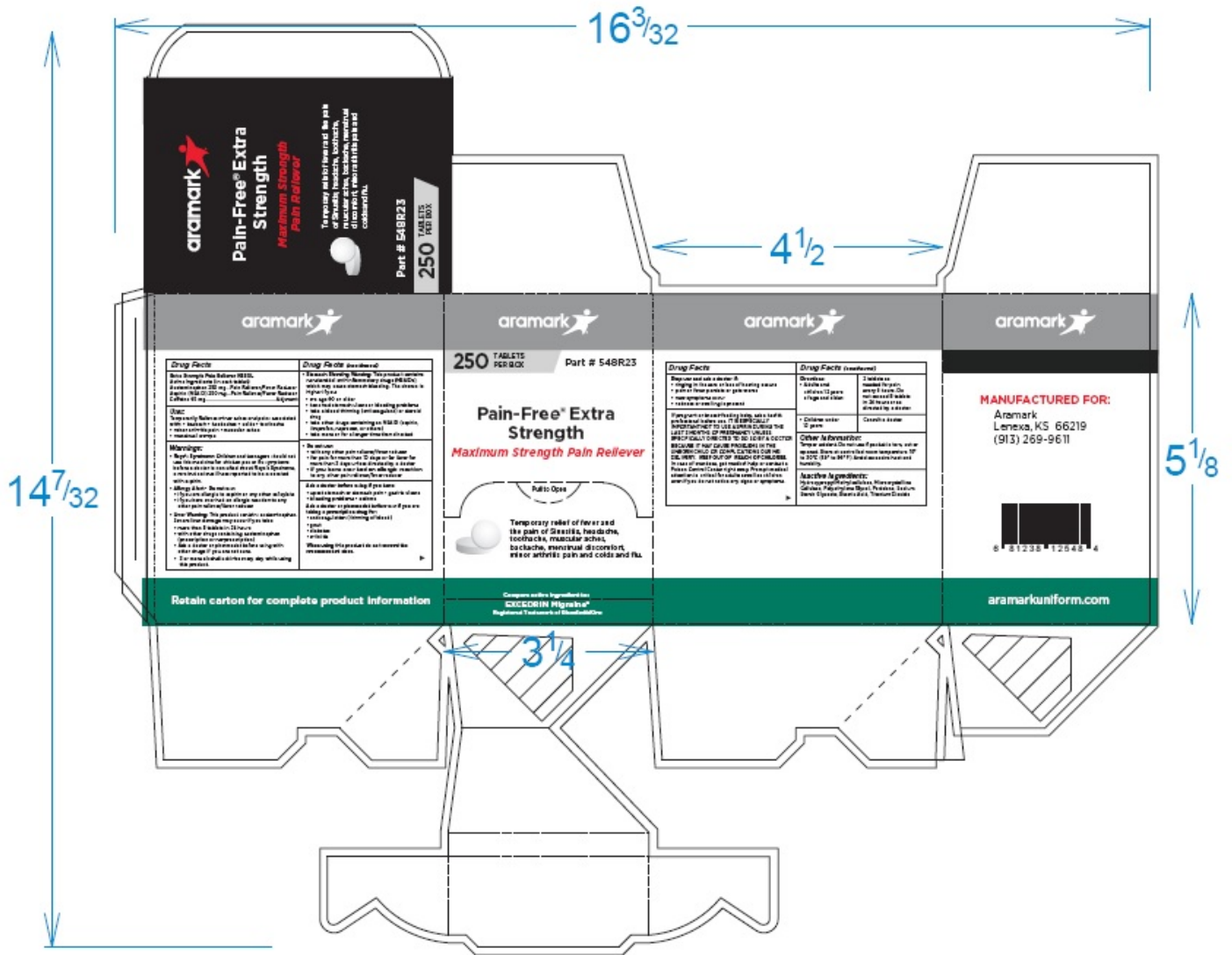
aramarkuniform.com

Retain carton for complete product information

100 Tablet Box



250 Tablet Box



2-Tablet Packet



PAIN FREE PLUS

X-Strength Pain Reliever

2 Tablets

Active Ingredients (In Each Tablet)	Purpose
Acetaminophen 250 mg.....	Pain Reliever
Aspirin 250 mg.....	Pain Reliever
Caffeine 65 mg.....	Stimulant

Uses: For the temporary relief of pain from: • headaches • muscular aches • menstrual cramps • toothaches • minor arthritic pain • colds

Warnings: Reye's Syndrome Warning: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye's Syndrome, a rare but serious illness reported to be associated with aspirin.

Liver Warning: This product contains Acetaminophen. Severe liver damage may occur if you take: more than 8 tablets in 24 hours. • with other drugs containing acetaminophen (prescription or non-pre-

FOR COMPLETE WARNINGS/CAUTIONS: SEE BOX

Warnings (continued)
 scription) • 3 or more alcoholic drinks every day while using this product.
Stomach Bleeding Warning: This product contains nonsteroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding. **The chance is higher if you:** have had stomach ulcers or bleeding problems • take a blood thinning (anticoagulant) or steroid drug • are age 60 or older • have 3 or more alcoholic drinks every day while using this product • take with other drugs containing an NSAID • take more or for a longer time than directed.
Keep out of reach of children.
Directions: Adults: 2 tablets with a full glass of water every 6 hours as needed. Do not exceed 8 tablets in a 24 hour period. Children under 12: Consult a doctor.
Other Information: Store at a controlled room temperature 15°-30° (59°-86°F). Tamper evident: Do not use packet if torn or cut.
 Contact: Aramark Lenexa, KS 66219

REV 3/2021

Made in USA

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ARAMARK PAIN-FREE EXTRA STRENGTH

acetaminophen, aspirin, caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81238-0560
Route of Administration	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
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	FR9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81238-0560-2	50 in 1 BOX	05/07/2021	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:81238-0560-3	125 in 1 BOX	05/07/2021	
2		2 in 1 PACKET; 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	05/07/2021	

Labeler - Western First Aid Safety DBA Aramark (043861524)

Registrant - Western First Aid Safety DBA Aramark (043861524)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRA SEAL CORPORATION		085752004	pack(81238-0560)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRA SEAL CORPORATION		944090448	manufacture(81238-0560)

Revised: 6/2021

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