

ARAMARK BACK RELIEF- magnesium salicylate 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 Back Relief

Active Ingredient (in each tablet)

Acetaminophen 250 mg

Cafeine 50mg

*Nonsteroidal anti-inflammatory drug

Magnesium Salicylate (NSAID) 290 mg

Purpose

AcetaminophenPain Reliever/Fever Reducer

CafeineAdjuvent

*Nonsteroidal anti-inflammatory drug

Magnesium Salicylate (NSAID)Pain Reliever

Uses:

Temporarily Relieves minor aches and pains associated with: • back pain • muscular aches

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: Saticylates (NSAIDs) may cause a severe allergic reaction which may include: • hives • shock • facial swelling • asthma (wheezing)

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 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
 - with any other product containing acetaminophen
 - right before or after heart surgery

Ask a doctor before using if you have:

- upset stomach or stomach pain • ulcers
- bleeding problems • high blood pressure • heart or kidney disease • taken a diuretic • reached age 60 or older

Ask a doctor or pharmacist before use if you are:

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug

When using this product do not exceed the recommended dose.

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.

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
- you feel faint, vomit blood, or have bloody or black stools.
- These are signs of stomach bleeding.

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 children even if you do not notice any signs or symptoms.

Directions:	2 tablets as
• Adults and children 12 years of age and older:	needed for pain every 4 hours. Do not exceed 8 tablets in 24 hours or as directed by a doctor.
• Children under 12 years:	Do not give to children under 12 years of age

Other Information:

- read all product information before using
- 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:

hypromellose, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, starch 1551, stearic acid, titanium dioxide

Product Labeling

aramark

100 Tablets

Part # 07333

Per Box

Back Relief

Pain Reliever/Fever Reducer

MANUFACTURED FOR:

Aramark
Lenexa, KS 66219
(866) 362-2691

aramarkuniform.com

Retain carton for complete product information



BACK RELIEF

Pain Reliever/Fever Reducer

2 Tablets

Active Ingredients Purpose (In Each Tablet)

Acetaminophen 250 mg.....pain reliever
 Caffeine 50 mg.....adjuvant
 Magnesium salicylate 290 mg (NSAID)*
pain reliever
 *nonsteroidal anti-inflammatory drug

Uses: Temporarily relieves minor back pain.

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: Magnesium salicylate may cause a severe allergic reaction which may include: • hives • facial swelling • asthma (wheezing) • shock.

FOR COMPLETE WARNINGS/CAUTIONS: SEE BOX

Warnings (continued)

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.

Keep out of reach of children.

Directions: Adults: take 2 tablets every 6 hours, not more than 8 tablets in 24 hours. Children under 12: Consult a doctor.

Other Information: Store at room a controlled 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

ARAMARK BACK RELIEF

magnesium salicylate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81238-1118
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	50 mg
MAGNESIUM SALICYLATE (UNII: 41728CY7UX) (SALICYLIC ACID - UNII:O414PZ4LPZ)	MAGNESIUM SALICYLATE	290 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81238-1118-1	50 in 1 BOX	06/14/2021	
1		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	06/14/2021	

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(81238-1118)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRA SEAL CORPORATION		944090448	manufacture(81238-1118)

Revised: 6/2021

Western First Aid Safety DBA Aramark