MAXIMUM ALLERGY RELIEF- acetaminophen, phenylephrine hcl 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 Maximum Allergy Relief

Drug Facts

Active Ingredient (in each tablet)

Acetaminophen 500 mg Phenylephrine HLC 5 mg

Purpose

AcetaminophenPain reliever/fever reducer Phenylephrine HLCNasal decongestant

Uses:

Temporarily relieves these symptoms associated with hay fever or other respiratory allergies and the common cold:

- headache
- sinus congestion and pressure
- nasal congestion
- minor aches and pains
- promotes sinus drainage
- temporarily reduces fever

Warnings:

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 6 tablets (3,000 mg acetaminophen) in 24 hours. 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

Allergy alert: acetaminophen may cause serve skin reactions. Symptoms may include:
•skin reddening •blister •rash
If a skin reaction occurs, stop use and seek medical help right away

Do not use

with any other drug containing acetaminophen. If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
if you are now taking a prescription monoamine oxidase inhibitor (MAOIs), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a

doctor or pharmacist before taking this product.

• if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have:

- liver disease
- diabetes
- heart disease
- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking the blood thinning drug Warfarin

When using this product do not exceed recommended dose

Stop use and ask a doctor if:

- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

Overdose warning: 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 take more than directed (see overdose warning)
- adults and children 12 years and over:
 - take 2 tablet every 4 hours
 - swallow whole; do not crush, chew or dissolve
 - do not take more than 6 tablets in 24 hours
- children under 12 years: ask 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:

Corn Starch, FD & C Blue #1 Lake, Microcystalline Cellulose, Povidone, Sodium Starch Glycolate, Stearic Acid, USP Purified Water

Package Labeling

aramark

100 TABLETS Part # 91933B PER BOX

Maximum Allergy Relief Pain Reliever/Nasal Decongestant

Temporary relief of headaches, sinus pain, nasal and sinus congestion, minor aches, pains, fever

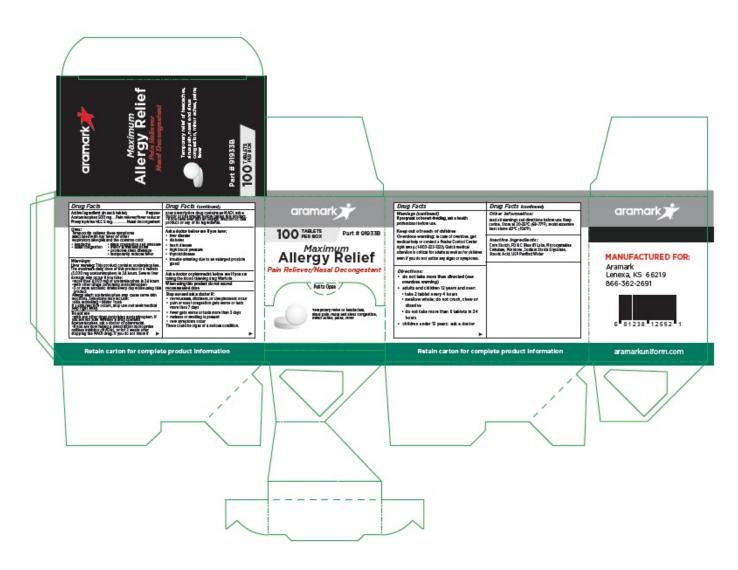
MANUFACTURED FOR:

Aramark Lenexa, KS 66219 (913) 269-9611

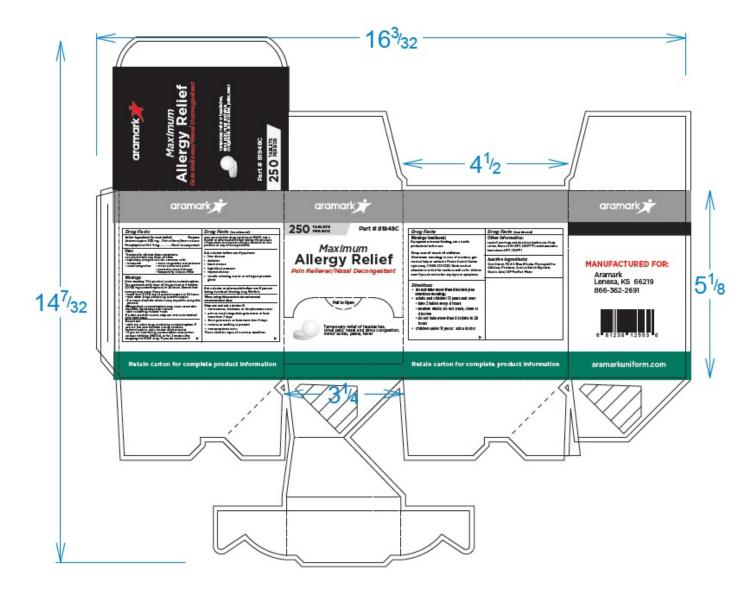
aramarkuniform.com

Retain carton for complete product information

100 Tablet Box



250 Tablet Box



2-Tablet Packet



disease . high blood pressure . thyroid

Warnings (continued)

disease • diabetes or • difficulty in urination due to enlargement of the prostate gland.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions: Adults and children 12 years of age and older: 2 tablets every 4 to 6 hours, not to exceed 8 tablets in any 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 form or cut.

Contact: Aramark Lenexa, KS 66219

FOR COMPLETE WARNINGS/CAUTIONS: SEE BOX

REV 3/2021

Made in USA

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MAXIMUM ALLERGY RELIEF

acetaminophen, phenylephrine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81238-0240
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1W5297W6MV)	PHENYLEPHRINE	5 mg		

Inactive Ingredients			
Ingredient Name	Strength		
STARCH, CORN (UNII: O8232NY3SJ)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POVIDONE (UNII: FZ 989GH94E)			
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)			

STEARIC ACID (UNII: 4ELV7Z65AP)

WATER (UNII: 059QF0KO0R)

Product Characteristics			
Color	blue	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	FR33
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81238- 0240-1	50 in 1 BOX	05/07/2021	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:81238- 0240-2	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 final	part341	05/07/2021	

Labeler - Western First Aid Safety DBA Aramark (043861524)

Registrant - Western First Aid Safety DBA Aramark (043861524)

EstablishmentNameAddressID/FEIBusiness OperationsULTRA SEAL CORPORATION085752004pack(81238-0240)

Establishment					
Name	Address	ID/FEI	Business Operations		
ULTRA SEAL CORPORATION		944090448	manufacture(81238-0240)		

Revised: 6/2021 Western First Aid Safety DBA Aramark